EPA NEW ENGLAND

U.S. ENVIRONMENTAL PROTECTION AGENCY

QUALITY MANAGEMENT PLAN

Revision 3
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EPA New England QMP

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INTRODUCTION

EPA New England's Quality Management Plan (QMP) describes the policies, procedures and management systems within the organization that govern quality assurance and quality control activities. This QMP is applicable to all environmental programs managed by EPA NE. It encompasses all environmental data operations and environmental technology activities performed directly by the Region; by our Federal, State, Tribal and local partners under interagency agreements and financial assistance agreements; and those performed for the Region by contractors funded by EPA; regulated entities; or potentially responsible parties.

The term "environmental data operations" refers to activities involving the collection, generation, compilation, analysis, evaluation and use of environmental data. The term "environmental data" refers to measurements or information that describe environmental conditions, locations, and processes; ecological or health effects and consequences; and the performance of environmental technology. Environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as databases or literature. Environmental technology includes the design, construction and operation of systems and components that prevent or remediate environmental contamination, and prevent, remove or monitor pollutants from process discharges.

The Regional Administrator and Regional Managers are fully committed to the implementation of an effective Quality System. Senior management realizes that support for the Quality System starts at the top and assures understanding and implementation of the Regional Quality System by issuing policy statements and performing assessments. EPA NE most recently confirmed its commitment to implementing a Quality System in the September 25, 2000 ***Policy Statement Reaffirming EPA New England's Commitment to Implementing the Regional Quality System*** (Appendix 1). Regional commitment is consistent with the objectives and goals of EPA Order 5360.1 A2 (QA Order), May 2000, and is documented in accordance with the EPA Quality Manual for Environmental Programs, 5360 A1 (*Quality Manual 5360 A1*), May 2000.

1.0 MANAGEMENT AND ORGANIZATION

1.1 EPA NE Mission Statement

The mission of the U.S. Environmental Protection Agency is to protect human health and to safeguard the natural environment - air, water, and land - upon which life depends (http://www.epa.gov/region1/about/index.html).

The Regional mission statement is: "It is our responsibility to maintain and enhance the natural

resources and environment which are foundations for a healthier, more beautiful New England for generations to come."

In addition, EPA NE articulates its vision for the environment and Regional plan for achieving EPA's ten environmental goals in the ***EPA New England FY 2001 Strategic Framework*** (http://r1intra1.r1.epa.gov:9876/ora/spframewkvcomplete.PDF). As part of the Regional strategic planning process, this plan is updated annually.

1.2 EPA NE Quality Assurance Policy

Quality assurance (QA) requirements are integrated into the Region's media programs which administer environmental data operations and environmental technology activities. It is EPA NE's policy that environmental data operations will result in the collection of environmental data of known and documented quality, suitable for its intended use, and that environmental technology activities will perform as specified.

This quality policy applies to all data collected and environmental technology activities performed by the Agency; by our Federal, State, Tribal and local partners under interagency agreements and financial assistance agreements; and for the Agency by contractors funded by EPA; regulated entities; and potentially responsible parties (PRPs).

The Regional Administrator and Regional Managers ensure that adequate resources, including intramural and extramural money, travel funds and personnel, are allocated to achieve EPA NE's quality policy.

1.3 ASSIGNMENT OF RESPONSIBILITY

In accordance with EPA Order 5360.1 A2, overall responsibility for the QA program in EPA NE rests with the Regional Administrator. However, the responsibility for developing and documenting Regional QA policies, procedures and guidance, overseeing the implementation and assessment of the Regional Quality System, and providing QA training has been delegated to the Regional Quality Assurance Manager (RQAM) in the Office of Environmental Measurement and Evaluation (OEME).

The EPA NE organizational chart is presented in Appendix 2. This chart identifies components of the EPA NE organization. The RQAM reports directly to the OEME Division Director. The dotted line between the RQAM and the Deputy Regional Administrator indicates that the RQAM has recourse to elevate issues to the next higher level of senior management, that is, the Deputy Regional Administrator.

Specific quality assurance responsibilities for Regional personnel are as follows:

1.3.1 Regional Administrator

As outlined in EPA Order 5360.1 A2 (also known as the QA Order), the Regional Administrator has overall responsibility for the Regional Quality System.

The Regional Administrator is responsible for:

1. Ensuring that all Regional components and programs comply fully with the requirements of the QA Order and the specifications of the *Quality Manual, 5360 A1*, including the preparation of a QMP for the Region, implementation of an effective Regional Quality System, and the timely submission of QA Annual Reports and Work Plans (QAARWPs) to OEI;

2. Ensuring that quality management is an identified activity with associated resources adequate to accomplish its program goals;

3. Ensuring that all applicable environmental programs delegated to State, Tribal, and local governments, or performed by organizations outside EPA pursuant to EPA regulations and requirements, comply fully with the requirements of the QA Order;

4. Ensuring that quality management and QA/QC training are provided to Regional management and staff;

5. Ensuring that Federal agencies and State, Tribal and local governments performing environmental data operations and environmental technology activities under assistance agreements with EPA have sufficient quality management and QA/QC training in order to perform the work successfully;

6. Ensuring that periodic management assessments of Regional organizational units performing environmental programs are conducted to determine the effectiveness of their mandatory Quality Systems; and

7. Ensuring that periodic management assessments of State, Tribal and local governments performing environmental programs are conducted to determine the effectiveness of their mandatory Quality Systems.

1.3.2 Regional Quality Assurance Manager (RQAM)

The Regional Administrator has delegated the responsibility and authority to implement an effective Regional Quality System to the RQAM. The RQAM utilizes the Quality Assurance Unit staff to assist in the day-to-day implementation of the EPA NE Quality System. Specific responsibilities of the RQAM include the following:

1. Facilitating the development and approval of the EPA NE QMP, conducting annual reviews and subsequent updates, as necessary, to the QMP within the five-year approval period;

2. Acting as official contact for EPA NE in all QA matters and communications to Office of Environmental Information (OEI) Quality Staff, as well as to other Regions and Programs within the Agency;

3. Providing expert assistance to EPA NE personnel on QA/QC policies, requirements and procedures applicable to the implementation of the EPA NE QMP for all environmental data operations and environmental technology activities;

4. Assessing QA/QC training needs and providing training for EPA NE programs; including Performance Partners and other Financial Assistance recipients such as States, Tribes, and interstate organizations;

5. Preparing Regional QA policies, procedures and guidance to facilitate implementation of national QA requirements;

6. Ensuring that organizations receiving Federal funds from EPA NE have approved QMPs in place and operate effective Quality Systems;

7. Ensuring that a systematic planning process is used to determine technical and QA/QC activities for intramural and extramural environmental data operations and environmental technology activities, that the results of the planning process are documented in planning documents, such as a QAPP or SAP, and that technical activities are documented in Standard Operating Procedures (SOPs).

8. Reviewing and approving QA planning documents including QMPs, QAPPs, and SAPs for intramural and extramural environmental data operations and environmental technology activities prior to initiation of field activities, and delegating approval authority for QA project plans in accordance with Section 7.2.

9. Providing technical assistance to media programs in support of the Regional Quality System;

10. Conducting Technical Systems Audits (TSAs); identifying deficiencies; documenting findings; determining corrective action recommendations; and monitoring the effectiveness of the implemented corrective actions;

11. Conducting Management Systems Reviews (and other Quality System Assessments) to monitor compliance with Quality System requirements; identifying strengths and weaknesses in the programs; documenting findings; requiring documented responses and corrective actions to findings; and performing follow-up reviews to assess the effectiveness of the implemented corrective actions;

12. Working with EPA NE programs to ensure appropriate, effective QA language is developed and incorporated into contracts, financial assistance agreements, memoranda of understanding/agreement, administrative orders, consent decrees, and other agreements which address environmental data operations and environmental technology activities;

13. Providing input to and comment on Agency-wide QA policy by performing peer review of documents and/or participating in national workgroups; and

14. Preparing QA Annual Reports and Work Plans (QAARWPs) and submitting to EPA NE's Leadership Team and the OEI Quality Staff.

Requests for QA services and support are tracked through the QAU Request for Assistance (QAU RFA) Process. The QAU RFA process and tracking system are described in the ***EPA NE, QAU Request for Assistance Standard Operating Procedure***, Draft Revision July 2001.

1.3.3 Office Directors

Office Directors are responsible for:

1. Ensuring that quality management is an identified activity with associated resources adequate to accomplish the program quality goals;

2. Ensuring that all staff members are familiar with the EPA NE QMP;

3. Ensuring that data of the type, quantity and quality necessary to support environmental decisions are obtained and used for both intramural and extramural programs;

4. Ensuring that all projects and tasks involving environmental data operations and environmental technology activities for both intramural and extramural activities are supported by a documented Quality System and covered by an approved QAPP which identifies and documents the project quality objectives;

5. Ensuring that approved QAPPs are reviewed annually and updated as necessary for continued adequacy;

6. Ensuring that sufficient auditing is performed to determine compliance with QA/QC requirements and that appropriate qualified personnel perform the auditing;

7. Ensuring that deficiencies identified in audits are corrected expeditiously; and

8. Identifying program-specific QA training needs and obtaining the required QA training.

1.3.4 Managers

As primary supervisors of Agency personnel, managers have the ability to directly evaluate the effectiveness of the planning, implementation and assessment components of EPA NE's Quality System. Managers are responsible for:

1. Ensuring that quality management is an identified activity with associated resources adequate to accomplish its program quality goals;

2. Ensuring that all sampling, analytical and/or data handling practices are documented in SOPs and that SOPs for all Branch/Unit programs are developed as functional, accurate documents that are initially approved and annually reviewed for continued adequacy;

3. Assessing the QA/QC training needs of their staff and arranging for such training with the RQAM;

4. Ensuring that staff utilize current guidance and requirement documents from both the OEI Quality Staff and the Regional QA Unit to assure uniform application of Agency QA policies and procedures;

5. Ensuring that projects are supported by a documented Quality System and that a systematic planning process is used to determine project quality objectives/data quality objectives (DQOs) for each environmental data operation and environmental technology activity conducted.

Subsequently, ensuring that the results of the planning process are sufficiently documented in approved QA planning documents, i.e., QAPPs and SAPs, prior to work initiation;

6. Ensuring staff participation in the review of project quality objectives/DQOs, and QAPPs, and other QA documents;

7. Ensuring that the QAPP has been implemented as described (i.e., that TSAs are performed as necessary) and that adequate review or validation steps have been employed to determine that only data of adequate quality are used in environmental decision-making; and

8. Ensuring that corrective actions are monitored for implementation and effectiveness.

1.3.5 Project Officers and Project Managers

EPA staff involved with environmental data operations and environmental technology activities performed under financial assistance agreements, contracts, and extramural, non-supported measurement (as by industry), are responsible for incorporating QA requirements into grant conditions, contracts, and voluntary, consentual or unilateral enforcement agreements, decrees and orders.

Project Officers, including Grant and Contract Project Officers, and Project Managers, including Remedial Project Managers (RPMs), RCRA Facility Managers (RFMs), and On-Scene Coordinators (OSCs), are responsible for:

1. Ensuring QA requirements are satisfied in all applicable acquisitions management activities;

2. Ensuring that all quality assurance deliverables (QMPs, or equivalent Quality System documentation, QA Management Reports, QAPPs/SAPs, SOPs, QC performance results, data quality reports, etc.) are provided to the Region;

3. Providing signature concurrence or approval on QAPPs;

4. Ensuring that QAPPs are approved prior to the initiation of data collection and implemented as written for all projects involving environmental data operations and environmental technology activities;

5. Ensuring that appropriate QA documentation, including copies of signed and completed QAPP/SAP Title and Approval Pages and PQO/DQO Summary Forms, are forwarded to the QA Unit prior to the initiation of environmental data operations and environmental technology

activities for programs that have been delegated QAPP approval authority; and

6. Ensuring that the QAPP has been implemented as described (i.e., that TSAs are performed as necessary) and that adequate review or validation steps have been employed to determine that only data of adequate quality are used in environmental decision-making.

1.3.5.1 Contract Project Officers

EPA Staff involved with preparing acquisition packages, and awarding and overseeing environmental data operations and environmental technology activities funded by EPA NE are responsible for ensuring that contractors are fully aware of and compliant with QA requirements.

In response to the 2000 Quality System Audit of this Region by OEI's Quality Staff , EPA NE's procurement process was revised to ensure compliance with and full participation by all Regional programs with applicable policies and regulations pertaining to quality in the procurement and management of contracts and work assignments.

Therefore, in addition to the responsibilities outlined above, Contract Project Officers are responsible for adhering to Procurement Policy Notice (PPN) 01-02 and the September 6, 2001 Regional policy statement ***Quality Assurance Requirements in Contracts and Procurements*** (Appendix 3). This policy statement outlines new policies, procedures and responsibilities for Contract Project Officers and Contracting Officers.

1.3.5.2 Grant Project Officers and Grant Specialists

EPA staff involved with awarding and overseeing environmental data operations and environmental technology activities funded by EPA NE are responsible for ensuring that financial assistance recipients are fully aware of and compliant with QA requirements.

In response to the 2000 Quality System Audit of this Region by OEI's Quality Staff, EPA NE's process for ensuring that financial assistance recipients meet QA requirements was revised to ensure compliance with and full participation by all Regional programs with applicable policies and regulations pertaining to quality in the award and management of grants, cooperative and interagency agreements. This new grants management process was initiated through the January 25, 2001 policy statement ***Revised Quality Assurance Requirements for Grants*** (Appendix 4), which states that:

> "A new grants process for the Region is being implemented to insure that the Region fully complies with Federal grant and cooperative agreement regulations pertaining to quality

assurance and to correct one of the deficiencies identified in the recent EPA NE Quality System Audit report. These policies and procedures were developed by our Grants QA workgroup and agreed to by the Senior Leadership team."

In addition to the responsibilities outlined above, Grant Project Officers and Grant Specialists are responsible for adhering to the February 20, 2001 policy statement ***Requirements for Implementing New Quality Assurance Policies for Financial Assistance Agreements*** (Appendix 5). This policy statement explains the new requirements and responsibilities for Project Officers and Grants Specialists in implementing the Quality Assurance (QA) policies and procedures for all financial assistance agreements. It outlines the new long-term EPA NE Grant QA Process and implements training and technical support to ensure consistent implementation of these new requirements.

1.3.6 Contracting Officers

EPA Staff involved with preparing acquisition packages, and awarding and overseeing environmental data operations and environmental technology activities funded by EPA NE are responsible for ensuring that contractors are fully aware of and compliant with QA requirements.

In response to the 2000 Quality System Audit of this Region by OEI's Quality Staff , EPA NE's procurement process was revised to ensure compliance with and full participation by all Regional programs with applicable policies and regulations pertaining to quality in the procurement and management of contracts and work assignments.

Therefore, in addition to the responsibilities outlined above, Contracting Officers are responsible for adhering to PPN 01-02 and the September 6, 2001 Regional policy statement ***Quality Assurance Requirements in Contracts and Procurements*** (Appendix 3). This policy statement outlines new policies, procedures and responsibilities for Contract Project Officers and Contracting Officers.

1.3.7 Office QA Contacts

In response to the 2000 Quality System Audit of this Region by OEI's Quality Staff , EPA NE's Senior Management committed to providing resources to ensure compliance with QA requirements in the award and management of financial assistance agreements. Specifically, the February 20, 2001 "EPA NE Grants QA Process" creates a new QA function and position within the organizational structure called an "Office QA Contact". Office QA Contacts are senior Agency personnel within each Office who assist staff in complying with the new Grants QA Process. Their responsibilities are detailed in Appendix 5.

1.3.8 Environmental Data Collection and Technology Staff

Environmental data collection and technology staff are responsible for:

1. Ensuring that work is conducted under approved QA planning documents;

2. Adhering to established sampling practices and procedures as prescribed in QA planning documents;

3. Adhering to good laboratory practices and methodologies as prescribed in QA planning documents;

4. Documenting any deviations from established methodologies, SOPs and QC protocols, and reporting the deviations to their supervisor; and

5. Identifying possible data quality problems and potential areas for quality improvements, and reporting these to their supervisor;

6. Identifying to management any defective, outdated, or deficient SOPs and suggesting routine operations which are in need of SOPs.

1.3.9 Dispute Resolution

For those situations in which issues regarding quality assurance are in dispute, resolution will be sought at the lowest management level possible. Such disputes may occur in situations involving technical issues (e.g., audits, data quality assessments) and management issues (e.g., QMP reviews, QAPP reviews, management system reviews and other Quality System assessments).

All parties will make every effort to resolve disputes through discussion and negotiation. Disagreements will be resolved at the lowest administrative level possible. EPA NE has trained mediators on staff to help facilitate issue resolution. Should agreement not be reached at this level, the issue will be resolved by the EPA NE Senior Management team (Office Directors). The Regional Administrator and the Deputy Regional Administrator have final dispute authority on all EPA NE quality issues.

1.4 ENVIRONMENTAL DATA OPERATIONS AND ENVIRONMENTAL TECHNOLOGY ACTIVITIES

This section identifies the major environmental data operations and environmental technology activities

covered by the Region's Quality Management Plan.

1.4.1 REGIONAL ADMINISTRATOR'S OFFICE

The Regional Administrator's (RA's) Office is the central, coordinating office of the Region, providing leadership, planning, oversight of key policy and program initiatives and resource management. While the Regional Administrator is ultimately responsible for the Regional Quality System, few direct environmental data operations or environmental technology activities are undertaken by this office. Therefore, its functions are not discussed in detail. However, if the RA's Office does undertake any environmental data operations or environmental technology activities (e.g., education grants, environmental impact reviews, etc.), all Regional quality policies and procedures are followed.

1.4.2 OFFICE OF ENVIRONMENTAL MEASUREMENT AND EVALUATION

The Office of Environmental Measurement and Evaluation (OEME) consists of three units which provide compliance and ambient monitoring of environmental conditions; design and interpretation of environmental indicators; and development and administration of the Regional Quality Management Plan.

1.4.2.1 Quality Assurance Unit

The QA Unit is responsible for managing the Regional Quality System; establishing quality policy, requirements, and procedures for all Regional environmental data operations and environmental technology activities; reviewing and approving intramural and extramural Quality Management Plans (QMPs), Quality Assurance Project Plans (QAPPs) and other QA documents (e.g, Sampling and Analysis Plans (SAPs), Laboratory Quality Assurance Plans (LQAPs), workplans, standard operating procedures (SOPs), etc); conducting Quality System Assessments and Technical Systems Audits (TSAs) to ensure that QA requirements are met; and providing technical assistance and guidance in the developing project quality objectives/DQOs, QMPs, QAPPs, SOPs, and in resolving sampling and analytical method and data usability issues.

Members of the QA Unit also provide training in Quality Assurance concepts, requirements, and practices to the various program offices, Agency contractors, and State, Tribal, and local governments, that are involved in environmental data operations and environmental technology activities.

In addition, the Unit is responsible for coordinating the Regional Peer Review Program; managing the Contract Laboratory Program (CLP) and Environmental Services Assistance Team (ESAT) contracts;

overseeing other CERCLA analytical service contracts; providing expert witness testimony; administering the CERCLA Performance Evaluation Program and the Discharge Monitoring Report for Quality Assurance (DMRQA) Studies for the National Pollutant Discharge Elimination System (NPDES) Program; managing the Drinking Water Certification Program; and supporting NELAP.

1.4.2.2 Investigations and Analysis Unit

The Investigations and Analysis Unit is comprised of two teams: The Chemistry Team and the Investigations Team. The Chemistry Team is responsible for performing chemical analyses of environmental samples or oversight of ESAT or external contract labs to support investigations conducted by OEP, OES, OSRR and CID. In addition, the Team provides technical assistance to the Regional media programs, State and local environmental agencies, private industries and independent laboratories in areas such as analytical methods, method development and field screening. Members of the Team provide consultation for legal cases, support for laboratory audits, screening for problem assessment and follow-up confirmatory analysis projects for the protection of ground water and drinking water supplies. Laboratory quality assurance and quality control procedures are documented in the Regional Laboratory Quality Assurance Plan.

The Investigations Team is responsible for providing field support, including sampling and regulatory compliance inspections, for the Air, Water and Waste Programs. These activities are performed to determine compliance with the applicable provisions of the CAA, RCRA, SARA, EPCRA, SWDA, CWA, and TSCA. The Team also provides field investigations support by conducting CERCLA site investigations and oversight of contractor investigations.

1.4.2.3 Ecosystem Assessment Unit

The Ecosystems Assessment Unit is a field service unit consisting of two teams: the Air Monitoring Team and the Water/Biology Team, that support Regional programs and States and Tribes, as well as nationwide monitoring initiatives. Under the Clean Water Act and Clean Air Act, the Unit assists States and Tribes in implementing and ensuring compliance with ambient monitoring programs. The Unit also develops environmental indicators and environmental assessment reports such as the annual State of the New England Environment Report.

The Air Team works with the States in implementing national and State ambient air monitoring programs including special projects and research on priority issues such as mercury. The Air Team supervises the collection and evaluation of air quality data collected by States and other entities in support of Regional and national monitoring, SIP planning and enforcement programs, and is responsible for reviewing all external air programs' QAPPs for environmental data collection and for

approving external air program standard operating procedures (SOPs). The Air Team insures that this air monitoring meets the Agency's required siting and design criteria, data collection techniques, quality assurance/quality control procedures and the data is reported to the Agency's national data system, AIRS, or another appropriate data system. Occasionally, the Air Team collects ambient air data for monitor siting, assessing air pollution impacts, supporting enforcement activities or to assess risks from hazardous waste sites. Other Air Team activities involve collecting collocated samples, conducting round robin checks, conducting performance and technical system audits to assess the quality of air data being reported to EPA and preparing reports on ambient air quality.

The Water/Biology Team assesses long-term water quality trends, assists State agencies, conducts special water quality surveys, and assists citizen volunteer monitors. The Team monitors the ecological health of New England's streams, lakes, and estuaries, provides support to Regional program offices, and assists States in regionally significant projects. The Team has a broad range of ecosystem assessment capabilities which are used to provide technical support, high quality environmental data, and expert advice in the areas of aquatic, wetland, and terrestrial biology. The types of field studies in which the Team may be engaged include baseline or ambient water monitoring, nonpoint and point source monitoring, time-of-travel and dispersion studies, sediment sampling, and biological and habitat assessment. Biology laboratory capabilities include water and sediment toxicity testing and microbiology. Data may be used for problem identification, determining compliance with State water quality standards, developing mathematical models for load allocations, preparing land use management plans, and reporting on the general health of New England's waters.

1.4.3 OFFICE OF SITE REMEDIATION AND RESTORATION

The Office of Site Remediation and Restoration (OSRR) is an integrated office for the management of hazardous waste sites. OSRR implements the Superfund program, including the clean up at National Priorities List (NPL) sites, site assessment, removal actions, emergency responses and counter terrorism activities. OSRR also administers the Region's Brownfields program, conducts oil spill preparedness and prevention activities, and oversees the Underground Storage Tanks (UST)/Leaking Underground Storage Tanks (LUST) programs and Corrective Action provisions of the Resource Conservation and Recovery Act (RCRA). OSRR provides various support functions for these specific programs including grants and contracts management, potentially responsible party (PRP) search investigations, cost recovery, human health and ecological risk assessment, hydrogeologic and geotechnical expertise, and records center, budget and information management.

During site assessment, OSRR, States, and their contractors undertake environmental data operations and environmental technology activities to characterize sites, determine whether sites are eligible for listing on the NPL and/or warrant a removal action.

At Fund-lead NPL sites, OSRR, States, and their contractors undertake environmental data operations and environmental technology activities to characterize sites, make site remediation decisions, and monitor remedy implementation and effectiveness. At PRP-lead and federal facility NPL sites, PRPs, federal facilities, and their contractors undertake environmental data operations and environmental technology activities to characterize sites, develop site remediation alternatives, and monitor remedy implementation and effectiveness. OSRR and the states oversee activities undertaken by the PRPs and federal facilities.

At Brownfield sites, OSRR contractors, States, local communities and their contractors undertake environmental data operations and environmental technology activities to characterize sites and develop site remediation alternatives. OSRR oversees activities undertaken by the States and local communities.

At RCRA corrective action sites, the owner/operator of the RCRA facility undertakes environmental data operations and environmental technology activities to characterize sites, develop site remediation alternatives, and monitor remedy implementation and effectiveness. OSRR and the states oversee activities undertaken by the owner/operator of the RCRA facility.

During an emergency response, OSRR, States and their contractors may undertake environmental data operations and environmental technology activities to characterize the spill or release, assess the risk to the surrounding population, and determine the appropriate response to contain or minimize the spread of the spill or release.

Currently, the UST/LUST programs and the corrective action provisions of RCRA are the only programs administered by OSRR that can be delegated to the States. The UST/LUST programs have been delegated to all six New England States and the corrective action provisions of RCRA have been delegated to the States of Maine, New Hampshire and Vermont. OSRR maintains oversite responsibility for the delegated programs in those states and directly implements the corrective action provisions of RCRA in the States of Connecticut and Rhode Island and the Commonwealth of Massachusetts.

OSRR also conducts compliance inspections under the UST program and the Spill Prevention Control and Countermeasures/Facility Response Plan programs. Environmental data operations and environmental technology activities are not conducted during these compliance inspections.

1.4.4 OFFICE OF ECOSYSTEM PROTECTION AND OFFICE OF ENVIRONMENTAL STEWARDSHIP

To adequately address the additional environmental data operations and environmental technology activities for EPA NE, the Office of Ecosystem Protection (OEP) and the Office of Environmental Stewardship (OES) are described together. The two offices are linked as they perform different functions for many of the same programs. The Office of Ecosystem Protection is a multi-media, ecosystem-based office that is in the process of establishing environmental standards and goals and works with States and communities to achieve these goals. The OEP deals with regulatory considerations and issues permits. The Office of Environmental Stewardship is a multi-media office which includes a flexible, enforcement unit and an expanded pollution prevention and technical assistance program. OES is the office responsible for monitoring how well the regulated community is complying with regulations, permit requirements and enforcement orders; and providing technical assistance in order for industry to remain compliant with regulations and permits.

Programs with significant environmental data operations and environmental technology activities are described below.

1.4.4.1 RCRA Program

The RCRA Program, with the exception of the RCRA Corrective Action program (OSRR), is permitted and monitored by OEP and enforced by OES. The Resource Conservation and Recovery Act (RCRA) was enacted in 1976 and major legislative amendments were adopted in 1984. The primary goals of RCRA are to protect human health and the environment from potential hazards of waste disposal; to conserve energy and natural resources; to reduce the amount of waste generated; and to ensure that wastes are managed in an environmentally sound manner. The responsibility for implementing the RCRA program is assigned to EPA and is accomplished through a compliance, enforcement and permit/closure process. Under the authority of EPA, States can be authorized to implement the RCRA requirements. All six New England States have been authorized to implement RCRA requirements. EPA maintains oversight responsibility for the authorized programs in those States.

The Hazardous Waste Program Office of OEP has the responsibility for issuing permits. The Hazardous Waste Program Office is also responsible for maintaining data on RCRA generators, transporters, and facilities.

<u>OEP Chemicals Management Branch</u>

For RCRA Subtitle C (hazardous waste), the Chemicals Management Branch of OEP authorizes equivalent State hazardous waste programs to achieve the GPRA goal that existing hazardous waste facilities will have approved controls in place to prevent dangerous releases to air, soil and

groundwater. This is primarily done by working with States who have received the authority to issue permits, and approve closure and post-closure plans. The Branch implements with the States "RCRAInfo", a national system that maintains information e.g. name, address, permit, compliance, enforcement and corrective action information on the hazardous waste handlers in our Region. In addition, the Branch implements with States "BRS", a national system on the use and handling of hazardous waste by the generators, treatment, storage and disposal facilities in our Region.

For RCRA Subtitle D (solid waste), the Branch reviews State municipal solid waste landfill permit programs to determine if they are "adequate" relative to the provisions published under 40 CFR Part 258. It also provides technical assistance to States on municipal solid waste landfill issues as resources allow.

OES RCRA Enforcement/Compliance Activities

To monitor compliance with a permit and to enforce compliance with RCRA permits, the RCRA Technical Unit of OES conducts field inspections. EPA and the States are responsible for conducting Comprehensive Groundwater Monitoring Evaluations (CMEs) and Compliance Evaluation Inspections (CEIs) in order to evaluate the facility's compliance with RCRA.

The CME determines the adequacy of the RCRA facility's groundwater monitoring system for complying with the applicable regulations contained in 40 CFR Parts 264, 265 (Subpart F) and 270 established under RCRA. Groundwater samples are collected and analyzed by EPA and/or the State.

The CEI evaluates the facility's compliance with RCRA and determines the need for enforcement actions or follow-up inspections/evaluations. Processing and reporting requirements are an essential part of the RCRA inspection program. The RCRA staff, States and contractors are responsible for conducting RCRA lead and oversight inspections as required by the Memorandum Of Understanding (MOA) with OECA. The OEME Investigation and Analysis Unit provides sampling support at the request of the OES compliance staff.

1.4.4.2 Water Programs

As in the RCRA program, the Office of Ecosystem Protection has permitting and monitoring responsibilities for the wide range of programs and regulations relating to the Region's water systems, from drinking water to wastewater. The Office of Environmental Stewardship supports these activities with field inspection and compliance activities as well as enforcement actions. The major data collection activities are divided into different areas, pursuant to supporting the Clean Water Act, the Marine Protection, Research and Sanctuaries Act, and the Safe Drinking Water Act.

Clean Water Act (CWA)

The individual State Offices of OEP, with the technical support of both the Municipal Assistance Office and the Water Quality Office of OEP, are responsible for implementing and monitoring programs which support all aspects of the Clean Water Act.

OEP staff implement the National Pollutant Discharge Elimination System (NPDES) permit program either directly or through oversight of a delegated State. For the National Pollutant Discharge Elimination System (NPDES) and Pretreatment programs, primacy has been delegated to four New England States, Connecticut, Rhode Island, Maine and Vermont. The State Office role is to provide technical assistance and oversight to the State-run programs. For the non-delegated New England States, Massachusetts and New Hampshire, the State Offices implement the NPDES and Pretreatment programs. Wastewater effluent limitations and other appropriate conditions are calculated primarily on the review and analysis of data from applications and discharge monitoring reports (DMR) along with other sources such as special studies, toxicity test reports, etc. Permittees report on the quality and character of their discharge based on the permit's requirements by submitting DMRs to the permitting authority. This data also is used by either OES and/or delegated State staff to assess a facility's compliance with its permit which may lead to subsequent enforcement activity.

OES staff monitor compliance with NPDES permits, initiate Federal enforcement actions for non-compliance and oversee State run enforcement programs. Permittee self-monitoring data are entered into the Permits Compliance System (PCS) and are evaluated by OES and the States to determine compliance with regulations and the need for follow-up enforcement actions. To determine compliance with NPDES permits, the Water Technical Unit of OES as well as the Investigation and Analysis Unit of OEME provide field expertise to conduct inspections of NPDES and pretreatment facilities. The performance of the Permittee's laboratory (either in-house or contract) is evaluated by the results of the analysis of the Discharge Monitoring Report Study for Quality Assurance (DMRQA) Performance Evaluation samples. The DMRQA program is coordinated by the QA Unit in support of permitting activities. OEP staff take follow-up actions based upon non-response or inadequate response. Adherence to the quality control analyses and acceptance criteria specified in the required methodologies helps to ensure the production of valid data by the Permittees.

States use water quality data obtained from various sources to develop their CWA Section 303(d) impaired waters list. OEP staff review and approve these lists which then serve as the basis for the total maximum daily load (TMDL) program. TMDLs are a tool used to identify specific pollutant reduction measures which when implemented will result in water quality standards and/or designated use attainment. The States develop most TMDLs based on sampling and analysis and often employ various models simulating differing water quality conditions. Some TMDLs utilize contract support

provided directly by the States or through organizations such as the New England Interstate Water Pollution Control Commission. OEP staff prepare TMDLs and usually rely on contractor assistance, with occasional OEME and State staff support, to generate the necessary water quality data or to develop the analytical methodology to support a specific TMDL.

OEP in partnership with the States also operates a myriad of CWA programs. States develop, revise and adopt surface water quality standards for review and approval by EPA (OEP). OEP, principally through its State Offices, also operates the non-point source program, the wetlands program and the National Estuary Program (NEP). EPA provides technical, grant and contract support for various projects and programs that meet specific requirements and environmental objectives. OEP staff are also responsible for NEPA compliance activities for NPDES new source performance standard category dischargers utilizing environmental impact and project information submitted by the proponent. Water Quality Unit and NPDES Task Force staff oversee the 301(h) discharge waiver program as implemented and monitored through NPDES permits. Wetlands program activities include reviewing and assessing the impact to wetland habitat and resources that specific projects/activities may exert as well as reviewing CWA section 404 Corps of Engineers issued permits.

To achieve these goals, the Office is responsible for the technical review and evaluation of environmental impact with regard to the disposal of wastes and dredged materials in marine and/or wetland areas in the Region. Monitoring requirements may be included in permits to identify the nature of the disposed material and its impact to the marine environment. Monitoring is also conducted to support enforcement actions as carried out by the Water Technical Unit of OES with field and analytical support from the Investigation and Analysis Unit of OEME.

Other programs managed by the State Offices, with the technical assistance of the Water Quality Office and the Municipal Assistance Office, in support of the Clean Water Act include the Groundwater Management program, the Clean Lakes program, the Nonpoint Source program, the Wetland Protection program, and the Marine, Near Coastal and Estuarine Management programs. For all of these programs, EPA NE works with the State, Tribal, and local governments to set environmental priorities and to develop statewide and place-specific environmental goals and strategies. Assistance to the States, Tribes, and local communities includes the provision of EPA expertise as well as funding through grants for projects that meet Federal, State, and local priorities.

Marine Protection, Research and Sanctuaries Act (MPRSA)

Under MPRSA (also commonly referred to as the Ocean Dumping Act), EPA (through the Water Quality Unit in OEP) is responsible for designating sites for the open water disposal of dredged material. Designation of these sites, located seaward of the territorial baseline, is subject to the

agency's voluntary EIS policy. OEP works closely with the Corps of Engineers to produce the data to support the designation or to dispose of dredged material.

Safe Drinking Water Act - OEP

Safe Drinking Water Act (SDWA) programs are found in nearly all EPA Offices. These SDWA programs include Public Water Supply Supervision (PWSS), Source Water Assessment and Protection (SWAP), Sole Source Aquifer (SSA), and Underground Injection Control (UIC). The PWSS program responsibilities include Drinking Water State Revolving Fund (OEP-CMU); Safe Drinking Water Information System (SDWIS) Management (OEP-CMU); PWSS implementation (OEP- State Units); State program, grants, and primacy oversight (OEP &OES); Enforcement (OES); Compliance Assistance (OES); Technology Transfer (OES); Lab Certification and Evaluations(OEME/OEP); Education/Outreach (All); and Technical Assistance (All). The Sole Source Aquifer Program, and Source Water Assessment and Protection activities are carried out in OEP, in the State Units and the Municipal Assistance Unit. Such responsibilities include State program and grant oversight, education/outreach, groundwater sampling and modeling, technical assistance, project review and approval, and geographic targeting. OEP has primary responsibility for State program primacy and grants oversight associated with the UIC program.

All six States have been delegated or authorized to enforce the following SDWA programs; PWSS Drinking Water, Wellhead Protection, UIC/Section 1422, and UIC/Section 1425.

1.4.4.3 Air Programs

As in the RCRA and Water programs, the Office of Ecosystem Protection has permitting and monitoring responsibilities for the various Regional programs to support the Clean Air Act (CAA). The Office of Environmental Stewardship supports these activities with field inspection and compliance activities as well as enforcement actions with support from the Office of Environmental Measurement and Evaluation. EPA NE is also involved in ambient air monitoring activities for national, State and local Air Monitoring Stations (NAMS/SLAMS), Photochemical Assessment Monitoring System (PAMS) networks, and particulate matter networks in the Region as previously described for the Ecosystem Assessment Unit of OEME.

Within OEP, the Air Quality Planning Office and Air Permit Programs Office are responsible for providing technical assistance to the States in planning, development, implementation and evaluation of their program plans and commitments. OEP's air program relies on ambient air quality monitoring data and source emission data collected by the New England States. The States collect ambient air quality monitoring data on air tonics, ground-level ozone, ozone precursors, lead, nitrogen dioxide, carbon

monoxide, sulfur dioxide, and particulate matter. All six States have been delegated or authorized to enforce the following CAA programs: Part 60/NAPS, Part/61 NESHAPS, Sect 52.21/PSD, Title V/Part 70, New Source Review, and Indoor Radon/Section 306. OEME works with the States to ensure that quality assurance requirements are met. The States also prepare inventories of emissions from sources. OEP requires the States to have adopted and used proper quality assurance requirements in preparation of these emission inventories.

For those instances which require enforcement and compliance action, the Air Technical Unit of OES plans and executes Federal enforcement actions. They also oversee State initiated enforcement programs under the Clean Air Act. Compliance data and emissions inventory data are entered into the AIRS database system which is monitored to ensure the integrity of the data.

Quality Assurance issues are addressed in SIPs which require Agency approval. For Emissions Testing programs, pre-test reports are submitted by the States and are reviewed by the Investigation and Analysis Unit of OEME. The tests are then observed and the data are evaluated to determine adherence to the pre-test reports.

1.4.4.4 Pesticides, Toxics and Radiation Office

Management of activities related to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Toxic Substances Control Act (TSCA) and the Region's radiation program is the responsibility of the Pesticides, Toxics and Radiation Office of OEP. The FIFRA program is delegated to the six New England States. As such, the Office is responsible for providing technical and financial assistance and oversight to the State programs. The TSCA program is primarily an enforcement effort with major emphasis on polychlorinated biphenyl (PCB) chemicals. The Toxics, Pesticides, and Federal Programs Unit of OES is responsible for providing enforcement support. Other programs managed by this Office include the Asbestos School Hazard Abatement Act (ASHAA) and Asbestos Hazard Emergency Response Act (AHERA).

1.4.4.5 Assistance and Pollution Prevention

The Assistance and Pollution Prevention (A and P2) Unit of OES uses the alternative approaches described below to encourage environmental compliance and beyond compliance changes. Few direct environmental data operations or environmental technology activities are undertaken by this office. If the A and P2 Unit does undertake any environmental data operations or environmental technology activities (e.g., pollution prevention grants, etc.), all Regional quality policies and procedures are followed.

New England Environmental Assistance Team (NEEAT)

The New England Environmental Assistance Team's (NEEATeam) mission is to help New England businesses and other regulated entities comply with environmental laws, benefit from pollution prevention and improve their environmental performance. The team focuses on assisting sectors that have been targeted as Regional or national priorities. Currently, NEEAT focuses its work on four sectors of the regulated community including: colleges and universities, metal finishing, municipalities, secondary schools, wood finishing, auto repair and refinishing, and mercury in hospitals and marinas.

Experimental Projects (Project XL and ECOS)

One of EPA's innovation efforts is known as "Project XL" (eXcellence in Leadership). Currently, the Region has 8 XL projects underway that test a wide variety of experimental approaches to how we regulate. Data on these projects is being collected and analyzed with a goal to make larger scale changes, where appropriate. Future XL projects that address Regional or national environmental priorities will be evaluated for project implementation. Further, the Region is also accepting project proposals from the States under the existing ECOS agreement.

Sustainable Practices

Promoting long-term and sustainable changes in behavior is a core element to the work in A & P2. Particular emphasis is placed on the use of environmental management systems and energy efficient practices, with a focus on promoting these practices within the priority environmental problems being addressed by other A & P2 efforts. Performance Track, in which Region 1 is an active participant (an original creator), as a national innovative program designed to test the use of EMSs in the regulated community nation-wide.

Center for Industry and Technology (CEIT)

The mission of CEIT is to be a window to resources, people and programs for the environmental technology industry in New England, and to promote the acceptance of innovative environmental technologies to solve the most significant environmental problems in New England. The Center offers services to address three specific problem areas that impede technology development and acceptance: 1) the access to information on government programs, 2) the access to information on new technologies for the regulated and non-regulated communities and 3) regulatory and institutional barriers. These services include: a web site; trade shows, Small Business Innovation Research (SBIR) program workshops; newsletters, and efforts to match technology developers with some of New England's priority environmental problems.

1.4.5 OFFICE OF ADMINISTRATION AND RESOURCE MANAGEMENT

The Office of Administration and Resource Management is a resource management office responsible for personnel, facilities, and space; financial management, including budgeting; information services; grants, contracts, and procurement; and other support services. No significant environmental data operations or environmental technology activities are performed directly by this office, therefore its support role for those activities is discussed below.

The Contracts and Procurement Office is responsible for ensuring all contracts and procurements incorporate quality assurance requirements in accordance with 48 CFR Part 46, PPN 01-02, and Regional quality requirements in contracts and procurements (Appendix 3). The Grants Management Office is responsible for insuring that all statutory and regulatory administrative requirements are addressed prior to the award of any grant or cooperative agreement. This includes the quality assurance requirements of 40 CFR and the Regional requirements for implementing new quality assurance policies for financial assistance agreements (Appendix 4 and 5).

The Information Resources Office and the Computing Technology Office are responsible for the storage, management and retrieval of mainframe data for PCS, CERCLIS, RCRIS, STORET and the AIRS database systems. These Offices are also responsible for the Region's Local Area Network, the purchase and upkeep of computer hardware and software and technical support for the Region's Geographic Information Systems (GIS) implementation. More detailed information on these functions can be found in Section 6.0 of this QMP.

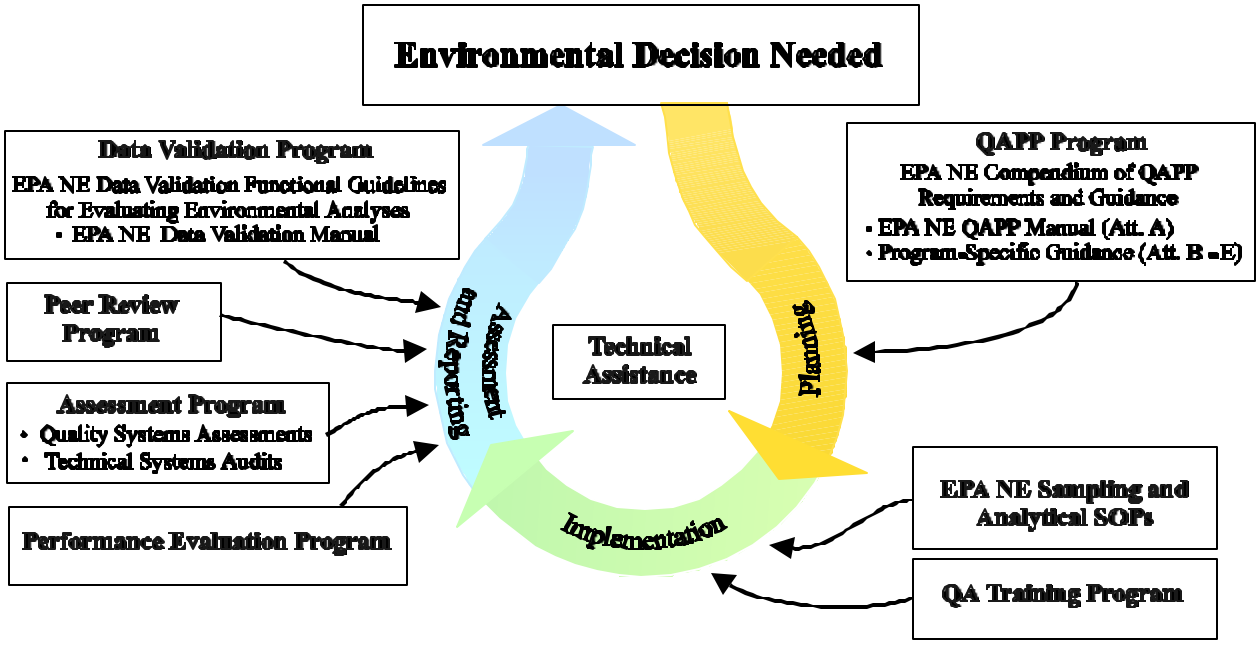
2.0 QUALITY SYSTEM COMPONENTS

The EPA NE Quality System provides an overarching management system designed to ensure the quality of work and services throughout the organization. The Regional Quality System provides the framework for planning, implementing, documenting and assessing Regional activities relevant to environmental data operations and environmental technology activities and for carrying out required QA and QC activities for the entire organization. The scope of this QMP precludes the need for additional QMPs by the organization, hence no approval procedures have been developed for review of QMPs internal to EPA NE. However, review and approval procedures for QMPs developed for extramural environmental activities are documented in the ***EPA New England Standard Operating Procedure for Reviewing Quality Management Plans,*** rev. 0, 5/01.

The EPA NE Quality System has evolved since first conceived in 1994. It is comprised of many functional components that have matured into Quality System programs and includes the following:

1. Quality Assurance Project Plan Program
2. Performance Evaluation Program
3. Assessment Program
4. Data Validation Program
5. QA Training Program
6. Peer Review Program

An overview of the Regional Quality System is presented below.



EPA NE Quality System and Supporting EPA NE Requirements and Guidance Documents

The Quality System programs and components are implemented by policy memoranda and through use of a variety of quality tools. These tools include a number of national and Regional requirements and guidance documents. Many of the Regional guidance documents may be obtained from the EPA NE web site: http://www.epa.gov/region01/topics/restech/qualsys.html and the national documents may be obtained from the Quality Staff web site: http://www.epa.gov/quality. The following table gives a brief overview of the Region's Quality System programs, components, available tools and the primary responsibilities for those programs. A detailed description of these components, and roles and responsibilities for their implementation, is provided in Elements 3-10 of this QMP.

Table 1. Summary of Regional Quality System Components, Tools and Responsibilities

Quality System • "Policy Statement Reaffirming EPA New England's Commitment to Implementing the Regional Quality System", 9/25/00			
Components	**Available Tools**	**National and/or Regional Requirements and Guidance**	**Responsibility**
1. Quality System	QMP	*EPA Quality Manual 5360 A1*	RQAM/QA Unit
2. Regional Planning	EPA NE Annual Strategic Framework Document	*Government Performance and Results Act (GPRA)*	Strategic Planning Team
3. Annual Quality System Review and Planning	QA Annual Report and Workplan	*EPA Quality Manual 5360 A1*	RQAM/QA Unit
4. QA Policies	Senior Management Memoranda	*EPA Quality Manual 5360 A1*	Senior Management; RQAM/QA Unit
Quality Assurance Project Plan Program • Officially implemented new EPA NE Quality Assurance Project Plan Policy", 10/1/99 • Program documented in the *EPA NE Compendium of QAPP Requirements and Guidance*, 10/1/99 • Tracking Systems - QAU Request for Assistance (RFA) Database - New England Sample Tracking System (NESTS) - QAPP/QMP Grants Tracking Database			
Project Planning	EPA NE Systematic Planning Process	*EPA NE Compendium of QAPP Requirements and Guidance* with Attachments A-E	Managers; Project Personnel
Project Planning Documentation	Data Quality Objective Summary Form	Appendix 2 *of EPA NE Compendium of QAPP Requirements and Guidance*, with Attachments A-E	Managers; Project Personnel
Project QA Documentation	QAPPs	*EPA NE Compendium of QAPP Requirements and Guidance* with Attachments A-E	Managers; Project Personnel

Project QA Planning Documentation Review	QAPP Review Procedures	*EPA NE QAPP Review Standard Operating Procedure, 2/24/99, Draft*	RQAM/QA Unit
Implementation • Tracking Systems - New England Sample Tracking System (NESTS) - Performance Evaluation Assessment and Control (PEAC) Tools - QAU RFA Database			
Delivery of Analytical Services (DAS)	Sampling and Analytical Procedures and Guidance for EPA Superfund/RCRA Contractors	*Region 1 ARCS Delivery of Analytical Services Pilot Program*, Final Report, 3/15/94	RQAM/QA Unit
Representative Sampling	Sampling SOPs	http://www.epa.gov/region01/topics/restech/qualsys.html	Project Personnel
Field Analytics	Field Analytical SOPs	http://www.epa.gov/region01/topics/restech/qualsys.html	RQAM/QA Unit
OEME Sampling, Analytical, etc. SOPs	OEME SOPs	OEME/Allshare	OEME
Performance Evaluation Samples	PEAC Tools	*EPA Region 1 Performance Evaluation Program Guidance*, rev. 7/96	RQAM/QA Unit
Assessment Program • Program documented in *EPA NE Assessment Program*, 12/99, Draft • Tracking Systems - Performance Evaluation Assessment and Control (PEAC) Tools - Assessment Tracking System (ATRACK) - QAU RFA Database			
Management Assessment	Quality System Assessments, Reviews and Audits	*EPA NE Assessment Program*, 12/99, Draft *EPA NE Management Systems Review SOP*, 4/19/96	RQAM/QA Unit; Managers

Project Assessment	Technical Systems Audits -Field Sampling Technical Systems Audits (TSAs) -Field Analytical TSAs -Field Laboratory TSAs -Fixed Laboratory TSAs -Split Sampling and Analysis Audits -Data Package TSAs -Data Validation TSAs	*EPA NE Assessment Program*, 12/99, Draft *EPA NE Technical Systems Audit SOP*, 6/28/96 Project-Specific Audit Checklists and Audit Reports	RQAM/QA Unit; Managers; Project Personnel
	Performance Evaluation Samples	*EPA NE Performance Evaluation Program Guidance*, 7/96	RQAM/QA Unit; Project Personnel

Data Validation Program

- Program documented in *EPA NE Data Validation Functional Guidelines for Evaluating Environmental Analyses*, 12/96
- Tracking Systems
  - QAU RFA Database
  - New England Sample Tracking System (NESTS)
  - Government Inspection Activities Database (GIAD)

Data Assessment	Data Verification and Validation Criteria and Procedures	*EPA NE Data Validation Functional Guidelines for Evaluating Environmental Analyses*, 12/96 with Attachments A-Q	RQAM/QA Unit; Managers; Project Personnel
Data Usability Assessment	Data Usability Assessment Procedures	*EPA Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA/G-9)* *EPA NE QAPP Manual*, Section 20	RQAM/QA Unit; Managers; Project Personnel
Data Validation Oversight/Methods Review Program	Delivery of Analytical Services Contractor Oversight Memoranda	*EPA NE Data Validation Functional Guidelines for Evaluating Environmental Analyses*, Part I: Data Validation Manual, 12/96	RQAM/QA Unit; Managers; Project Personnel

<table>
<tr><td colspan="4">QA Training Program
• Implemented in “Development of EPA NE QA Training Modules”, 11/21/95
• Tracking Systems:
- QA Training Tracking Database</td></tr>
<tr><td>QA Training Program</td><td>QA Unit Training Modules</td><td>EPA Guidance for Developing a Training Program for Quality Systems (QA/G-10)

Standard Operating Procedure for the EPA NE QA Training Tracking System, 7/99</td><td>RQAM/QA Unit; Managers</td></tr>
<tr><td colspan="4">Peer Review Program
• Documented in Science Policy Council Handbook, Peer Review, 2nd edition, 12/00
• Tracking Systems
- National 2001 Science Inventory Database</td></tr>
<tr><td>Peer Review Program</td><td>National Peer Review Process

Peer Review Call Letters/Memoranda</td><td>Science Policy Council Handbook, Peer Review, 2nd edition, 12/00

Regional Processes for Identifying Candidates for Peer Review</td><td>Peer Review Coordinator; Office Peer Review Contacts; Peer Review Product Coordinator; Peer Review Leaders; Managers</td></tr>
</table>

3.0 PERSONNEL QUALIFICATIONS AND TRAINING

The achievement of Regional goals and objectives requires that all management and staff performing tasks related to environmental data operations and environmental technology activities have the necessary skills and knowledge to effectively accomplish their work. EPA NE is committed to ensuring that all employees are fully qualified and maintain an appropriate level of knowledge of QA principles and tools.

3.1 Commitment to Training

It is the policy of EPA NE to provide and/or make available to management and staff the training, including QA training, necessary to carry out their work successfully. Senior management takes the lead in ensuring that the necessary levels of technical proficiency and QA knowledge are maintained.

3.2 Qualifications

EPA policy is that personnel must meet the minimum qualifications defined in the Office of Personnel Management (OPM) Qualification Standards Handbook for their series and grade. The application of sound QA policies and procedures requires that all staff who perform QA tasks possess an appropriate level of knowledge of QA procedures and principles.

The EPA New England Human Resources Office has responsibility for ensuring that all EPA positions are properly classified as to job series, title, and grade based on an analysis of the duties of the position, as defined and submitted by the supervisor and manager of record for the position, in compliance with OPM's position classification system. Each classified position defines the principal duties, the knowledge required, the level of supervision, and a variety of other factors used to determine the final grade level of the position. The knowledge, skills, and abilities needed to perform the work of the position are incorporated as part of the qualifications identified to fill the position. Applicants for QA positions must be able to demonstrate that they have the required knowledge, skills, and abilities to meet the qualifications of the position.

It is also essential that the supervisor and manager of record for positions with QA responsibilities ensure that incumbents of those positions have performance plans, critical job elements and performance standards reflecting their QA work each year, in compliance with EPA's performance management system. In this manner, employees with QA responsibility will have identified measurable goals and objectives for each year.

3.3 Professional Development and Training

EPA NE provides professional development and training through the Regional Training Office and through external sources. Needs assessments are conducted periodically to identify training needs for the Region. In-house or EPA-sponsored training courses are e-mailed to all Regional staff each month and posted on the Regional web site. Registration for training offered by the Training Office is accomplished electronically. The Regional Training Office is responsible for maintaining records of employee training received through the Regional Training Office and training received from sources external to the Region.

3.4 Certifications

Formal certifications are required for various personnel in the Region. For those personnel involved in auditing and certifying State SDWA programs, special training is required and certificates are received upon successful completion of the training course. Certificates are kept on file by the person certified. Copies should also be retained in personnel records.

For those personnel involved in managing financial assistance agreements and contracts, including Grant Project Officers and Contract Project Officers, successful completion of the Contract Officer Representative training is required for certification.

3.5 Training for Quality

The QA Unit works with the Regional Training Officer, Office Directors and their staff to assess QA training needs for Regional management and staff. Also, in conjunction with the Office Directors, State and Program Directors, the QA Unit identifies, develops and provides QA training to EPA contractors, and States and other Federal financial assistance recipients.

QA training is based on prioritized needs and implemented as resources permit. EPA NE has a QA Training Coordinator responsible for planning and coordinating QA training for Regional management and staff, EPA contractors, other Federal Agencies and their contractors, and States and other Federal financial assistance recipients. In addition, the QA Training Coordinator maintains the QA Training Database to track attendees of QA Unit training courses. This information is used to monitor QA training within the Region and is compiled and presented in the QA Annual Report and Workplan.

3.5.1 QA Training Needs Assessment

EPA NE uses a five-fold approach to identifying Regional QA training and retraining needs.

1. **Employee training needs are identified and documented during annual PERFORMS reviews**. The PERFORMS process identifies training and developmental needs to enhance or

improve an employee's current performance, or may specify remedial training needed to correct deficiencies in performance or educational preparation. Training may include technical, quality assurance, operational, non-technical, and managerial topics.

2. Training needs are identified through internal and external audits and management system reviews. For example, the January 2000 Quality Staff Audit performed by the Quality Staff of the Office of Environmental Information identified noncompliance with Quality System documentation pertaining to Federal Assistance Agreement Regulations. In response to this finding, a "Grants QA Workgroup" was convened. This workgroup developed and presented mandatory "QA Awareness Training" to all Regional grants specialists, project officers and their supervisors.

3. Training is developed when new national and Regional QA policies are issued. For example, the Regional Quality Assurance Project Plan Program was restructured in 1999, as described in the ***EPA New England Quality Assurance Project Plan Policy*** (Appendix 6), and the requirements of this program were documented in the ***EPA NE Compendium of QAPP Requirements and Guidance***, 10/1/99. The need for extensive training to implement and institutionalize the new QAPP program was identified. Audience-specific QAPP training modules were developed and presented to familiarize Regional management and staff, EPA contractors, financial assistance recipients, and other Federal Agencies with the requirements and procedures of the new program.

4. The QA Unit identifies training needs while providing technical assistance. The EPA NE QA Unit expends a significant portion of its FTE on technical assistance to the Region. Working closely with Regional staff while attending project planning meetings, reviewing QA documents, and performing project assessments and data reviews, provides the QA Unit with firsthand knowledge of the degree of quality awareness on the part of management and staff. The QA Unit utilizes this direct input to identify quality training needs and to develop audience-specific quality training course modules.

5. The QA Unit utilizes the Quality Assurance Training Tracking Database (QA-TTD) to document training and to identify additional training needs. The QA Training Database is used to document what QA training has been provided to different Regional Offices, Branches, Units and Teams and their external constituents, and to identify gaps and additional training needs.

3.5.2 QA Unit Staff Training

The RQAM evaluates the training needs of the QA Unit staff members during the PERFORMS process. In general, training for QA Unit Staff includes attendance at one or more job-related, short-term training courses, workshops and/or professional meetings each year. Active membership in professional organizations is encouraged and noted in annual performance reviews.

In addition, the RQAM is committed to maintaining a team with diversified knowledge that is capable of providing consistent technical QA assistance and guidance. To this end, the RQAM ensures that staff are cross-trained and participate on ad-hoc teams assembled to address specific Regional QA needs and training.

3.5.3 Financial Assistance Agreement Recipients and Contractors

The qualifications and training of personnel performing environmental data operations and environmental technology activities funded by EPA NE under Federal financial assistance agreements and contracts are evaluated through Quality System Assessments, technical system audits, and pre-award reviews, as applicable. Appropriate corrective actions are recommended. In addition, EPA NE provides QA training based on prioritized programmatic needs as resources permit.

3.5.4 EPA NE QA Modular Training Program

The EPA NE Training Program was instituted on November 21, 1995 in a memorandum titled ***Development of EPA NE Quality Assurance Training Modules*** (Appendix 7). The Regional QA training program is based on a modular approach; modules may be presented as stand-alone training sessions, combined with other modules and/or integrated with training courses developed by OEI Quality Staff. The Regional training modules are designed and tailored to meet identified Regional needs. The list of available modules is also provided in Appendix 7.

3.5.5 QA Training Records -QA Training Provided by the Region

The QA Training Tracking System (QA-TTS) supports the EPA NE QA training program by tracking the QA training provided by the QA Unit to Regional personnel and stakeholders. The QA-TTS is comprised of:

- QA Training Files;
- QA Training Tracking Database; and
- QA-TTS Standard Operating Procedure, Rev. 2, July 8, 1999, which describes the scope of the system and data entry procedures.

3.5.6 QA Training Records - QA Training Provided by other Sources

QA Training provided by sources external to EPA NE is tracked by the Regional Training Office in the Workforce Competency Development System (WCDS).

4.0 PROCUREMENT OF ITEMS AND SERVICES

It is EPA NE's policy to specify the designated quality assurance and quality control requirements when acquiring items and/or services that relate to environmental data operations and environmental technology activities. Within EPA NE, procurement functions are conducted in accordance with the Federal Acquisition Regulations and related Agency policies, directives, and guidance. Contractors, suppliers and financial assistance recipients are responsible for the quality of work performed or items and services provided by their subcontractors and suppliers.

A graded approach to implementation of quality assurance and quality control requirements is a key tenet of the EPA NE Quality System. The RQAM has the authority to establish "equivalent" quality requirements. Any deviations from the requirements set forth below must be documented in the program/project/contract file.

4.1 Contracts

All procurements and contracts originating in EPA NE must meet established administrative and quality assurance requirements in the latest edition of the:

- Federal Acquisition Regulations;
- ***Acquisition Handbook***; and
- ***Contracts Management Manual***.

Regional procurement policy has been revised to conform with the new Federal Acquisition Regulations (FAR) 46.202-4 and 52.246-11, as well as Procurement Policy Notice (PPN) No. 01-02, the interim guidelines for EPA's quality requirements for use in acquisitions. Implementation of the new Regional procurement policy was outlined in the September 6, 2001 policy statement ***Quality Assurance Requirements in Contracts and Procurements*** (Appendix 3). This policy statement outlines new policies, procedures and responsibilities for Contract Project Officers and authorized contracting officer representatives. In those procurements and contracts where higher level quality requirements apply, appropriate contract clauses must be used.

In addition, for all new proposed procurements and contracts originating within EPA NE, the Contract Project Officer or authorized contracting officer representative must complete a form for *Region I QA Review For Extramural Projects (Contracts)*, otherwise known as the QAR Form (Appendix 3), prior to forwarding a request for procurement/contract placement. Part II of the QAR Form identifies whether environmental data operations or environmental technology activities will be performed under the procurement or contract.

If there will not be any environmental data operations or environmental technology activities, then the Contract Project Officer or authorized contracting officer representative must sign Part II of the QAR Form and include the signed form with the procurement request package.

Part III of the QAR Form identifies the specific quality requirements applicable to the procurement/contract for both pre- and post-award. The available options include QMPs, joint QMPs/QAPPs, various types of QAPPs (programmatic, contract, and project-specific), and specification of equivalent documentation. If there will be environmental data operations or environmental technology activities, then the Contract Project Officer or authorized contracting officer representative must complete Parts II and III of the QAR Form in consultation with the RQAM. Upon completion, the form must be signed by both the Contract Project Officer or authorized contracting officer representative and the RQAM, and then submitted as part of the procurement request package. The Contracting Officer will incorporate the appropriate contract clauses that are applicable to the quality requirements specified in the QAR Form.

If quality requirements are applicable to the proposed new procurement/contract and QA documents are required pre-award, the RQAM reviews the pre-award QA documents to determine the capability of the contractor to adequately collect data of known and documented quality and/or to adequately perform environmental technology activities. The Contract Project Officer or authorized contracting officer representative is responsible for submitting contractor QA documents to the RQAM.

After contract award, when requesting services either through the issuance of a work assignment, task/delivery order or other ordering mechanism, the quality requirements specified in the approved QAR Form for the contract must be followed. The Contract Project Officer or authorized contracting officer representative must submit documentation of compliance with the required quality requirements for each work order to the RQAM. This documentation will be defined on a contract-specific basis. Electronic notification is acceptable. Whether done electronically or by hard copy, the Contracting Officer must receive this documentation for the official contract files.

For use of procurements/contracts originating outside of EPA NE (i.e., those not issued by the Regional Contracting Officers), the appropriate Federal (or other) Contracting Officer or Project Officer must determine whether quality requirements have been identified. The RQAM is available for guidance on what quality requirements are applicable.

4.2 Financial Assistance Agreements

Financial Assistance Recipients are required to conform with applicable QA requirements as specified in:

- 40 CFR Part 30, Grants and Agreements with Institutions of Higher Education, Hospitals and Other Non-profit Organizations;
- 40 CFR Part 31, Uniform Administrative Requirements for Grants and Cooperative Agreement to State and Local Governments; and
- 40 CFR Part 35, State and Local Assistance.

The Office of Grants and Debarment document, ***Implementation of Quality Assurance Requirements for Organizations Receiving EPA Financial Assistance,*** is utilized by the Region during "Project Officer QA Awareness Training" to educate management and staff on QA requirements as they pertain to grants and cooperative agreements. Specifically, the QA requirements include QMPs and QAPPs for organizations funded to conduct environmental programs that include "direct measurements or data generation, environmental modeling, compilation of data from literature or electronic media, and data supporting the design, construction, and operation of environmental technology."

4.2.1 Grants and Cooperative Agreements

In response to the 2000 Quality System Audit of this Region by OEI's Quality Staff, EPA NE's process for ensuring that financial assistance recipients meet QA requirements was revised to ensure compliance with and full participation by all Regional programs with applicable policies and regulations pertaining to quality in the award and management of grants, cooperative and interagency agreements. This new grants management process was initiated through the January 25, 2001 policy statement ***Revised Quality Assurance Requirements for Grants*** (Appendix 4), which states that:

> "A new grants process for the Region is being implemented to insure that the Region fully complies with Federal grant and cooperative agreement regulations pertaining to quality assurance and to correct one of the deficiencies identified in the recent EPA NE Quality System Audit report. These policies and procedures were developed by our Grants QA workgroup and agreed to by the Senior Leadership team."

In addition to the responsibilities outlined above, Grant Project Officers and Grant Specialists are responsible for adhering to the February 20, 2001 policy statement ***Requirements for Implementing New Quality Assurance Policies for Financial Assistance Agreements*** (Appendix 5). This policy statement explains the new requirements and responsibilities for Project Officers, Grants Specialists, and the QA Unit in implementing the Quality Assurance (QA) policies and procedures for all financial assistance agreements. It outlines the new long-term EPA NE Grant QA Process and implements training and technical support to ensure consistent implementation of these new requirements.

Basically, for continuing program grants that involve environmental data operations and environmental technology activities, QMPs and QAPPs are required. For one-time grants that involve environmental data operations and environmental technology activities, just QAPPs are required

The process is as follows:

The Grant Project Officer determines if a QAPP is needed and the decision is documented on the Assistance/Agreement Request for Award/Action memorandum.

If a QAPP is not needed, the appropriate Office QA Contact must concur with that decision on the Assistance/Agreement Request for Award/Action memorandum as well.

If a QAPP is needed, the Grant Specialist incorporates the appropriate special grant condition(s) into the grant award. Any modifications to the special grant condition language must be reviewed and approved by the RQAM. Once the grant is awarded, the Grant Project Officer works pro-actively with the grantee to insure that the QAPP is developed, completed and submitted to the RQAM for review and approval. Grant Project Officers must also provide signature approval concurrence on QAPPs produced under financial assistance agreements.

QMPs and QAPPs shall be prepared, reviewed and approved in accordance with the specifications provided in Section 7.0 of this QMP. All QMPs and QAPPs are reviewed and approved by the RQAM, as received from the Grant Project Officer or directly from the financial assistance recipient. The only exception to the required RQAM approval is when QAPP approval authority has been delegated as discussed in Section 7.6.

A grants quality assurance database, the QAPP/QMP Tracking System, was instituted to help ensure and document compliance with Agency and Regional quality policies and requirements. The QAPP/QMP Tracking System was designed to facilitate tracking of QAPPs and QMPs required as the result of a grant condition for grants awarded in EPA NE. Specifically, the system tracks the receipt and approval of these documents for grants with quality requirements. The tracking system also promotes communication and coordination across offices within the Region regarding grant QA requirements. Grant Project Officers and QA Unit personnel both have defined responsibilities for entering data in the tracking system.

4.2.2 Interagency Agreements

Interagency agreements that are funded by EPA are subject to the same requirements outlined in 4.2.1 above for grants and cooperative agreements. However, EPA cannot unilaterally impose such requirements. Therefore, they are incorporated into individual agreements by Project Officers or

Project Managers.

5.0 DOCUMENTS AND RECORDS

EPA NE adheres to the most current version of the following regulations, guidance and policies pertaining to documents and records as they pertain to program requirements:

- 44 U.S.C. Chapter 31, Records Management by Federal Agencies
- 44 U.S.C. Chapter 33, Disposal of Records
- 18 U.S.C. Chapter 101 Records and Reports
- Paperwork Reduction Act of 1995
- OMB Circular A-130, Management of Federal Information Resources
- 36 CFR Chapter XII, Subchapter B
- ***Records Management Manual***, EPA Order 2160
- ***Information Resources Management Manual***, EPA Directive 2100, Chapter 10, Records Management
- Agency Records Disposition Schedules
- Draft Agency File Plan
- ***A Guide to Conducting a Records Management Baseline Assessment***
- ***Using the Federal Records Center: A Guide for Headquarters Staff***
- National Archives and Records Administration Documents

For CERCLA, the following regulations, guidance and policies pertaining to documents and records are also adhered to:

- 40 CFR Part 300, National Contingency Plan
- ***U.S. EPA New England Region Records Management Program Manual***
- ***File Structure Guidance for Region I Superfund NPL Site Files, Superfund Removal Site Files, and Federal Facility Site Files*** (Rev. September 1997)
- ***Plan/Classification for EPA New England Region OSRR*** (OSRR Standard Operations Manual)

Maintenance of documents and records (both printed and electronic) associated with the mission of a given program or project is the responsibility of the Office which has primary responsibility for that program or project. Each Office is responsible for establishing and implementing procedures for identifying, controlling, filing, storing, protecting, and accessing documents and records. Documents include guidance documents, policy memoranda, written procedures, and QA management and project planning documents. Records provide objective evidence of an item or process and include data recording media, photographs, drawings, magnetic tape.

The QA Unit is responsible for documents and records associated with the implementation of the EPA NE Quality System.

5.1 Process for Identifying Quality-Related Documents and Records Requiring Control

5.1.1 Quality System

The QA Unit identifies specific documents and records that require control in the supporting guidance and program documents, which are used in the implementation of the Regional Quality System.

The QA Unit describes the control of quality-related documentation and records in the following documents:

- ***EPA NE Quality Management Plan,*** 9/01 Draft Revision;
- ***EPA NE Compendium of Project Plan Requirements and Guidance***, 10/99;
- ***EPA NE Assessment Program***, 12/99;
- ***EPA NE Data Validation Functional Guidelines for Evaluating Environmental Analyses***, 12/96**;**
- ***EPA Region 1 CSF Completeness Evidence Audit Program,*** 7/91;
- ***EPA Region 1 Performance Evaluation Program Guidelines,*** 7/96 Revision; and
- ***The Regional Sample Control Center Guidance for the Contract Laboratory Program and Delivery of Analytical Services Program for EPA New England***, 11/96.

These documents require the control of QA-related documents including, but not limited to:

- Project-specific Quality Assurance Project Plans;
- Generic Program Quality Assurance Project Plans;
- Standard Operating Procedures;
- Data Validation Memoranda and Reports;
- Technical System Audit Reports;
- Data Usability Assessment Reports;
- Quality System Assessment Reports; and
- QA Document Review Reports.

These documents also require that Regional Offices involved in environmental data operations and environmental technology activities control QA-related records (both written and electronic) including, but not limited to:

- Chain of Custody Records;
- Field Sampling Notes;
- Field and Fixed Analytical Records for the transfer, preparation, and analysis of samples;
- Sample Result Forms; and
- Communication Records.

The processes for preparing, reviewing, approving, issuing, using, verifying, validating and revising quality-related documents and records are described therein. The QA Unit is responsible for and has been delegated the authority to develop Regional requirements and guidance documents relevant to QA-related documents and records. The QA Unit assesses the conformance to Regional requirements through its Assessment and Data Validation Programs.

5.1.2 EPA NE Media Programs

Identifying documents and records (both printed and electronic) associated with the mission of a given program or project is the responsibility of the Regional Office which has primary responsibility for that program or project. Each Regional Office is responsible for establishing and implementing procedures for filing, storing, protecting, and accessing documents and records. It is the Manager's responsibility to ensure that required procedures are implemented. In addition, programs involved in environmental data operations and/or environmental technology follow Regional requirements for quality-related records and documents.

5.2 Process for Ensuring Documents and Records Accurately Reflect Completed Work

Each Regional Office is responsible for establishing and implementing procedures for ensuring consistency and technical accuracy. It is the Manager's responsibility to ensure that records and documents accurately reflect completed work.

5.3 Process for Maintaining Documents and Records

Each Regional Office is responsible for establishing and implementing procedures for maintaining quality-related documents and records, including transmittal, distribution, retention, access, preservation, traceability, retrieval, removal of obsolete documentation, and disposition.

At a minimum, the QAPP and the final project/site report are to be filed together. The specific file system utilized by each program is the responsibility of the individual Managers. In addition, for those programs delegated QAPP approval authority, the authorized program representative must forward to the QA Unit, for each project-specific QAPP, the following:

- **Copy of completed Title and Approval Page with approval signature; and**
- **Documentation of systematic planning process use, e.g., DQO/PQO Summary Form or other documentation.**

In addition, the QA Unit follows the procedures documented in ***Standard Operating Procedures for Quality Assurance Unit File System***, Draft 8/01, for filing, retaining, accessing, storing, archiving, retrieving, removing expired records and obsolete documentation and disposing of QA-related records and documents.

5.4 Process for Establishing and Implementing Chain of Custody and Confidentiality Procedures

Each Regional Office is responsible for establishing and implementing chain of custody and confidentiality procedures. It is the Manager's responsibility to ensure that required procedures are implemented. These processes should be designed to comply with EPA Order 2160 and EPA Directive 2100, Chapter 10.

6.0 COMPUTER HARDWARE, SOFTWARE AND INFORMATION PRODUCTS

The Environmental Protection Agency's ability to fulfill its mission is dependent upon a strong information technology infrastructure and reliable electronic information products. These have to be able to support a broad range of mission objectives, all of which require information integration and dynamic communication among EPA offices and its partners.

The Office of Environmental Information (OEI) is responsible for managing the EPA's information function including its collection, technology infrastructure and access. In that role, OEI has established information technology (IT) standards to ensure that information technology components integrate properly into the overall IT infrastructure, and has developed information product standards to ensure that information deliverables can be readily integrated and used for a varied range of EPA and other uses.

6.1 EPA NE Information Management Systems

All information management system development, improvements, and updates will comply with EPA Directive 2100, ***Information Resources Management Policy Manual*** and will include a systematic and comprehensive dialogue among the data providers, data and system users, and system developers, prior to the design and installation of the system.

It is Regional policy to work closely with Regional information system customers, as well as OEI and national program offices as appropriate, on all phases of system development, improvements, and updates including contractor developed and other entity developed systems. During all life cycle phases of information management systems, Region 1 will comply with requirements within EPA Directive 2100, ***Information Resources Management Policy Manual*** and the most current version of the Region 1 ***System Life Cycle Document***. Compliance with the applicable information resource management standards will ensure that all hardware and software configurations are developed, installed, and tested prior to use, to guarantee they perform as expected, are well documented, and meet user requirements.

6.2 Hardware and Software Requirements

In addition to the ***System Design and Development Guidance and Operations and Maintenance Manual***, Region 1 will comply with the Office of Administration and Resource Management's ***Delegation of Procurement Authority Guide***. This will ensure that purchased hardware and software will meet user requirements and will comply with OEI's technology and procurement guidelines. Other pertinent hardware and software standards utilized by the Region include: EPA's Network Security guidelines, Energy Star and Section 508 guidelines, and EPA's Hardware and

Software Standards Roadmap (http://basin.rtpnc.epa.gov:9876/etsd/itaroadmap.nsf).

6.3 Data Standards

All Federal Agencies are required to adhere to Federally mandated data standards and regulations. It is the policy of Region 1 to comply with all applicable regulations, guidance, executive orders, and internal policy documents concerning data standards. These include:

The EPA's core information data standards: the Locational Data Accuracy Standard, the Facility Identification Standard, the Groundwater Data Element Standard, the Chemical Abstract Number Standard, and the Electronic Transmission of Lab Measurements Standard. It is the responsibility of each individual Region 1 office to be aware of the current standards and regulations. These standards and polices can be found at http://www.epa.gov/irmpoli8/.

Other relevant data product standards include: standards for web product development contained in the EPA Web Guide (http://www.epa.gov.webguide/deploy/mail) and two related EPA Orders: 2190.1 Cookies and other User Tracking Methods and 2190.2 Children's Privacy and Copyright Issues.

The EPA Data Standards Program is established and documented in the EPA Directive 2100 ***Information Resources Management Policy Manual***. Within EPA, adherence to data standards policy is accomplished through the direction of OEI. EPA's information product-related policies apply to all EPA organizations and personnel, including contractors, Senior Environmental Employee (SEE) Program participants, and other personnel assigned to EPA who design, implement, and maintain information management systems and products for Region 1 and EPA.

7.0 PLANNING

EPA New England uses systematic processes to plan all aspects of environmental work, including strategic goal setting, quality management planning at the organizational level, and project planning.

7.1 EPA NE Annual Strategic Plan

EPA NE has initiated a Strategic Planning Process which sets the direction and priorities for the Region. This ongoing planning process integrates the activities of the Region, assigns resources to areas that support EPA NE's mission, and moves the Region toward achieving its vision.

7.2 QA Annual Work Plan

The QA Order requires that EPA organizations submit a Quality Assurance Annual Report and Work Plan (QAARWP) to the Quality Staff of the Office of Environmental Information. EPA NE prepares a yearly work plan that addresses both the QA activities of line management and those of the QA Unit including the oversight of delegated activities.

7.3 Quality Management Plans

In accordance with the QA Order, both EPA organizations and those funded by EPA that are performing environmental data operations and environmental technology activities are required to operate under Quality Systems that conform to ANSI/ASQC E-4 (E-4) specifications. EPA implements those E-4 specifications through the ***EPA Quality Manual for Environmental Programs***, 5360 A1, and ***EPA Requirements for Quality Management Plans,*** (EPA QA/R-2), as described below.

For all EPA organizational units governed by the QA Order, the ***EPA Quality Manual for Environmental Programs***, 5360 A1, provides program requirements for implementing the mandatory Quality System as defined in the QA Order. Therefore, for EPA NE, our Quality System is planned, developed, and documented in this QMP in accordance with the ***EPA Quality Manual***. The QMP is reviewed and approved by the Quality Staff of the Office of Environmental Information. The implementation of the QMP is a shared responsibility of all Regional personnel and is overseen by the RQAM. The RQAM is responsible for keeping the QMP current, performing annual reviews of the Quality System, and resubmitting the QMP whenever revisions are necessary or at a minimum of every five years.

For organizations funded by EPA NE, a Quality System is planned, developed and documented in accordance with ***EPA Requirements for Quality Management Plans,*** (EPA QA/R-2), or in an

equivalent document as specified by the Region. Equivalent documentation of a Quality System is determined on a case-by-case basis by the RQAM. All extramural QMPs and other organizational Quality System documentation are reviewed and approved, at a minimum, by the RQAM. The QA Unit reviews and approves QMPs in accordance with the ***EPA NE Standard Operating Procedure for Reviewing Quality Management Plans***, 5/01. Federally funded organizations are responsible for keeping their QMPs (or equivalent documentation) current, performing annual reviews of their Quality Systems, and resubmitting their QMPs whenever revisions are necessary, when so directed by EPA NE, or at a minimum of every five years. Appendix 8 lists the status of State QMPs and Appendix 9 lists the status of Agency contractor QMPs.

7.4 Systematic Planning Process

EPA NE requires that all environmental data operations and environmental technology activities conducted by or funded by the Agency must be planned using a systematic process based on the scientific method.

EPA NE has adopted a systematic planning process to ensure that all environmental data operations performed by and for the Region will collect, generate and use data or information that are of the type, quality and quantity that will support environmental-decision making. A systematic planning process is also used to plan environmental technology activities to ensure that performance needs are met.

The new EPA NE systematic planning process was officially implemented through the October 1, 1999 policy statement ***EPA New England Quality Assurance Project Plan Policy*** (Appendix 6). The systematic planning process adopted by this Region is outlined in the October 1, 1999 ***EPA NE Compendium of QAPP Requirements and Guidance***, Diagram 1. of ***Attachment A: EPA NE QAPP Manual***, and the process is fully described in the ***EPA NE QAPP Manual***. These documents describe a planning process that includes the following:

- identification and involvement of project manager, lead organization (sponsoring organization) and responsible official, project personnel, stakeholders, data generators and suppliers and data users and decision-makers;
- description of identifying project goals, quality objectives, and environmental questions that must be addressed;
- development of a realistic project schedule, including resources, budget, milestones and any applicable requirements;
- identification of the type and quantity of data needed;
- specifications of performance criteria for measuring quality and determination of required QA and QC activities to assess the quality performance criteria;
- description of how, when and where the data will be obtained, and a discussion of

constraints and limitations on data collection;
- description of process for obtaining and evaluating secondary data, and a discussion of constraints and limitation of use of secondary data;
- selection of assessment activities to demonstrate that project activities will be conducted as planned; and
- how data will be analyzed, evaluated, reviewed and assessed against its intended use and the quality performance criteria.

The ***EPA NE Compendium of QAPP Requirements and Guidance*** serves to implement national QA requirements for systematic project planning and the preparation of QAPPs as described in the ***EPA Quality Manual***, 5360 A1 (for EPA organizations) and in the ***EPA Requirements for Quality Assurance Project Plans***, EPA QA/R-5 (for contractors and financial assistance recipients).

For many routine monitoring programs, the National Program Offices in EPA Headquarters have developed programmatic data quality objectives and model QAPPs. In these cases, EPA NE utilizes the national guidance and model QAPPs and incorporates them by reference into the applicable program planning documents. The attachments to the ***EPA NE QAPP Compendium*** include Regional and program-specific guidance documents, and form the basis of the Regionally adopted graded approach to project planning, documentation, and assessment. The QAPP requirements are determined using the systematic planning process and are commensurate with the intended use of the data.

The RQAM and QA Unit staff are available for technical assistance in planning projects and developing project quality objectives. However, the ultimate project and data quality decisions lie with the program. It is the program's responsibility to properly plan the project to ensure the collection of data of the type and quality necessary to support its decisions. Therefore, Project Managers and Project Officers are responsible for ensuring that a systematic planning process is used in project planning.

7.5 QA Project Plans

The EPA NE QAPP Program requires that the results of the systematic planning process be documented in a QAPP (or in an equivalent QA planning document). Equivalent documentation is determined on a case-by-case basis by the RQAM and is based upon the project quality objectives and the intended use of the data.

QAPPs are required for all environmental data operations and environmental technology activities. Project Managers and Project Officers are responsible for ensuring that the results of the systematic planning process are documented in an approved QAPP prior to the start of work.

The Region has adopted a graded approach to project activities, including the preparation and review of QAPPs, and the assessment of project activities. To be approved, a QAPP must, at a minimum, include sufficient information to support the achievement of project objectives.

7.5.1 Types of QAPPs

EPA NE supports the use of two types of QAPPs, as defined in the ***EPA NE QAPP Compendium***: project-specific QAPPs and generic program QAPPs. EPA NE encourages the use of generic program QAPPs whenever practicable and the QA Unit provides technical assistance to the States, Tribes and local governments in developing them. Approved generic program QAPPs are supported by site-specific or project-specific addenda (such as Sampling and Analysis Plans), which address the issues unique to each site or project. The generic program QAPP will specify the preparation, review, and approval of site-specific or project-specific addenda.

Refer to Appendix 9 for the status of Agency Contractor Generic Program QAPPs within the Region.

7.6 QAPP Approval Authority

All environmental data operations and environmental technology activities conducted by EPA or funded by EPA must have an approved QAPP in place prior to the initiation of work. The RQAM has the responsibility and authority to approve all extramural and intramural environmental data operation and environmental technology QAPPs, unless delegated as part of the Regional QMP (see 7.6.1 and 7.6.2 below). In addition, Project Officers must also provide signature approval concurrence on QAPPs produced under financial assistance agreements (Appendix 4 and 5).

7.6.1 Authorizing EPA Program Personnel to Approve QAPPs

In accordance with the QA Order, the RQAM may authorize a representative, as defined in the approved QMP, to review and approve QAPPs. In EPA NE, the RQAM has authorized the Project Managers in the Superfund and RCRA Corrective Action programs to review and approve QAPPs prepared for the EPA by contractors, other Federal Agencies, States, and those submitted by the regulated community under voluntary and consentual or unilateral enforcement agreements, decrees and orders. Superfund and RCRA Corrective Action Project Managers are required to provide to the QA Unit a copy of the DQO/PQO Summary Form (or equivalent documentation of systematic planning) and a copy of the completed and signed "Title and Approval Page" prior to the initiation of work.

7.6.2 Authorizing State Agencies to Approve QAPPs

The RQAM may authorize a State Agency or one of its environmental programs to approve its own

QAPPs. For example, QAPP approval authority could be delegated to an entire Department of Environmental Protection, or the approval authority could be limited to just the Water Quality program. Delegation of this approval authority is contingent upon:

- having a fully implemented and effective Quality System in place, including sufficient resources;
- using a systematic process to plan projects, determine project quality objectives, select technical activities and necessary QA/QC activities for the project;
- documenting results of the systematic planning process in a QA planning document, e.g. QAPP;
- having an effective, written procedure for reviewing and approving QAPPs prior to the initiation of work; and
- having the ability to adequately assess the implementation of QAPPs, and to perform necessary corrective actions.

To date, EPA NE has delegated site-specific/project-specific addenda approval authority to selected States who have current approved generic program QAPPs for Superfund.

7.7 EPA NE QAPP Review and Approval Process

The Regional review procedures for QAPPs are detailed in the ***Region 1, EPA NE Quality Assurance Project Plan Review Process***, Draft 2/24/99. The review process is comprised of two steps: a Level 1 QAPP Completeness Check and a Level 2 Technical QAPP Review.

7.7.1 Time frame for Reviewing and Approving QAPPs

The time to review and approve a QAPP is dependent upon whether or not the initial submission of the QAPP provides sufficient and appropriate project information. In order to allow for comment and response, organizations should submit an approvable QAPP to the QA Unit a minimum of 30 calendar days before the initiation of work. An approvable QAPP is one that is complete and contains sufficient and appropriate information to describe project activities and objectives.

7.8 Implementing and Revising QAPPs

Implementation and revision of QAPPs under the EPA NE QAPP program is discussed in Section 6.0 and 7.0 of the EPA NE QAPP Compendium. In summary,

- Approved QAPPs must be implemented as prescribed;
- When procedures and/or activities described in the original QAPP must be modified

immediately to achieve project objectives, then the QAPP must be amended. This amendment must be reviewed and approved in the same manner as the original QAPP;

- QAPPs must be kept current and revised whenever necessary, or when so directed by EPA, or at a minimum of every five years until the project is completed; and
- The QAPP must be reviewed annually and this annual review must be documented in a letter to the EPA.

8.0 IMPLEMENTATION OF WORK PROCESSES

The policy of the Region is to implement data collection operations and environmental technology activities as described in the approved QAPP. Among other things, QAPPs are required to include a written description of all technical activities and QA/QC that will be performed. These descriptions may either be provided in the text of the QAPP document or as attachments of standard operating procedure documents. Sections 9, 10, 11, 12, and 15 of the ***EPA NE QAPP Manual*** identify the types of procedures/SOPs that should be included in a QAPP.

8.1 Standard Operating Procedures (SOPs)

For routine activities such as field sampling, analytical methods and data handling procedures, EPA NE develops and uses standard operating procedures (SOPs). These written protocols serve to ensure a standardized and consistent approach to work on an environmental project for a program. Standardization of sampling and analytical procedures provides a basis for generating representative data. In addition, SOPs include documented quality control provisions that are used to support the collection of data that will meet the measurement performance criteria for the project. Documented protocols also serve as a basis for performing technical systems audits.

8.2 QA Training on SOPs

To assist the Region in implementing its work procedures appropriately, the QA Unit developed and has presented a training module (QAB-Training Module #96) on SOPs. This training module deals specifically with the components of an SOP, and how to review an SOP to ensure that a project activity, as described, will achieve the data quality objectives. The SOP training emphasizes the following:

- what activities need an SOP;
- differences between published methods and organizational procedures;
- differences between vendor manuals and organizational procedures;
- what information to include in an SOP, including QA/QC procedures and criteria;
- how to review an SOP for procedural inaccuracies and inconsistencies;
- necessity of SOP approval signatures; and
- relevance of SOP revision numbers, and modification process.

8.3 Responsibility for SOPs

The responsibility for identifying operations needing SOPs, and for preparing, updating, approving, withdrawing and archiving SOPs rests with the Manager responsible for the routine use of the specific

procedure in conducting day-to-day activities. However, it is incumbent upon all staff to identify operations needing SOPs or revisions to existing SOPs.

Managers are responsible for ensuring that SOPs are implemented appropriately. Managers can use a variety of mechanisms to accomplish this, including direct oversight of work being performed, comparability of work products between staff, and results of assessments. SOPs are to be clearly and concisely written so that a person with a minimum-level technical background can follow the procedure without interpretation or assumption.

SOPs are initially prepared by staff and revised when necessary. Managers are responsible for the initial review, approval and subsequent annual review of SOPs. Current SOPs must be readily available to all personnel. Managers are responsible for ensuring that current SOPs are followed. Modifications to current procedures must be documented and have supervisory concurrence. Outdated SOPs are withdrawn from work areas and archived when no longer relevant.

The RQAM also identifies the need for standardized procedures through Quality System assessments and technical system audits, which identify areas of inconsistency that would benefit from standardized procedures. When this occurs, the QA Unit recommends the development of SOPs as a corrective action.

8.3.1 Responsibility for Quality-Related SOPs .

The QA Unit develops SOPs in accordance with ***Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents*** (EPA QA/G-6). The SOPs for the QA Unit are subjected to internal review and are approved by the RQAM or designee.

8.4 SOP Implementation

EPA NE uses the Regional processes described in the Assessment Program and described in Element 9 of this QMP to ensure that approved QAPPs, technical procedures and SOPs are implemented as written.

8.5 SOP Document Control

All QA planning documents, including SOPs, are subject to the document control procedures as described in Section 5.0 of this QMP.

8.5.1 QA Unit SOPs - Storage

For QA Unit SOPs, original, hard copies of the signed SOPs are retained by the QA Unit. Hard copies of current SOPs are maintained with the Regional Quality System documents. Outdated copies of the signed SOPs are archived in accordance with the Unit's archival procedures.

In addition, all QA Unit SOPs are stored electronically on the OEME allshare lan drive. Current SOPs are available to all QA Unit personnel and to other OEME personnel. Outdated SOPs are archived in electronic format and are available to OEME personnel for historical purposes.

Certain specialized SOPs, such as the EPA NE X-Ray Fluorescence Standard Operating Procedure, October 1996, are made available on the EPA NE web site.

9.0 ASSESSMENT AND RESPONSE

The EPA NE Quality System comprises four basic components: 1) planning, 2) implementation, 3) documentation, and 4) assessment. Assessment, the final component, is the evaluation process used to measure the performance or effectiveness of a system and its elements. Assessments are a learning process intended to increase understanding of the program or system being assessed, and to provide a basis for improving such programs or systems. Assessments identify problems, reveal areas of strength and weakness, and allow management to evaluate the organization's processes and performance.

To measure the effectiveness and performance of the EPA NE Quality System, the QA Unit coordinates an assessment program for Regional environmental programs. This assessment program is described in the ***Region 1, EPA New England Assessment Program***, 2/02.

9.1 Quality System Assessment

The EPA NE Quality System is assessed annually and the assessment documented in the QAARWP for the Region. Each October, the QA Unit requests, compiles and reviews information for Regional quality resources and activities including 1) quality management resources, 2) QA training, 3) quality management accomplishments, and 4) quality management assessments. For any area found to need improvement, an action plan is developed and incorporated in the QA Annual Work Plan as a QA activity for the coming year.

9.2 Conducting Assessments

The process used by the QA Unit for planning, implementing and documenting assessments and reporting results to management is described in our ***Assessment Program*** document. Specific procedures are detailed in the ***U.S. EPA, EPA NE Standard Operating Procedure for the Management Systems Review***, Rev. 1, April 1996 and the ***U.S. EPA Region 1 Standard Operating Procedure for Technical Systems Audits***, Rev. 0, June 1996, which are contained in Attachment A of the ***Assessment Program***.

Assessment Tools - Selection of the appropriate assessment tool is based upon the level or aspect of the Quality System being assessed or the stage of the project being assessed. The appropriate tool types for the various Quality System levels and project stages are outlined in the tables below.

Quality System Assessments

Level	Appropriate Tool Type	Comments and Examples
General, overall review of Quality System	Management Systems Review (MSR)	Emphasizes the collection of information; often used the 1st time a Quality System is assessed
Comprehensive audit of Quality System	Quality System Audit (QSA)	Assesses conformance to a documented Quality System through collection of documented evidence of implementation
Audit of a specific product or service of the Quality System	Product/Service Quality Audit (PSQA)	Evaluates performance as well as the Quality System itself in meeting customer needs (i.e., Data Validation TSA)
Audit of a specific process of the Quality System	Process Quality Audit (PQA)	Examines effectiveness of a specified portion of the Quality System (i.e., audits of the state programs for drinking water)

Project (Technical) Assessments

Project Stage	Appropriate Tool Types	Examples
Planning	QA Project Plan Review Site Scoping Visit	QAPP Review - 2 Levels
Sampling	Technical Systems Audit (TSA)	Field Sampling TSA (Low Flow Ground Water TSA)
Analysis	Technical Systems Audit; Performance Evaluation Sample (PES)	Field Analysis TSA Field Lab TSA Fixed Lab TSA
Data evaluation and reporting	Audit of Data Quality (ADQ)	Data Package TSA Data Validation - 3 Tiers
Usability	Data Quality Assessment (DQA)	Data Usability Assessment Peer Review

Specific tools utilized by the Region are described in tabular form in the ***Assessment Program*** for both Quality System (management) and technical assessments along with frequency requirements and recommendations. Organizational applicability, sources of assessment criteria and guidance references are also included in the tools' tables.

Frequency - The EPA NE Quality System is reviewed annually as described in Section 9.1. Additional Quality System assessments and major technical assessments to be conducted by QA personnel are outlined each year in the QA Work Plan.

Project assessments are stipulated in individual QA project plans. EPA NE strategy is to conduct technical assessments as early as practicable in the course of a data collection activity to identify potential problems and prevent the generation of data that do not meet the needs of the project. Data quality assessments may be useful in the early stages of a project or at the end of a project to look at overall data usability. Performance evaluation samples are specified for every sample delivery group, for each matrix, analytical parameter and concentration level, unless none exist.

The Quality System and technical assessments conducted by EPA NE QA personnel each year are summarized in the Assessment Tracking System, ATRACK, which is included in the EPA NE QAARWP.

9.3 Assessor Qualifications, Responsibilities and Authority

Qualifications - Within the QA Unit, all personnel conducting Quality System assessments have taken the Agency assessment training course, Management Systems Review Workshop, offered by the OEI Quality Staff (formerly QAD). This course or equivalent training is required for new QA Unit assessors. Regional personnel participating in assessments of the State drinking water programs are required to have taken the auditing course presented by EPA- Cincinnati and received a certificate for the areas they are auditing (i.e., organic chemistry, inorganic chemistry and/or microbiology). Personnel conducting audits under NELAC are required to have the appropriate NELAC assessment training (accreditation authority or laboratory auditor).

Quality System assessors need to have direct experience with the implementation of Quality Systems before conducting assessments. Similarly, personnel leading technical systems audits should have experience or familiarity with the technical procedures they are auditing. Assessors in the QA Unit have been cross-trained (e.g., both field sampling and laboratory analysis) so that in addition to their own areas of technical expertise, they are familiar with other areas as well. When resources are available, a minimum of two assessors is preferred for conducting each assessment. In addition to increasing the degree of experience, this practice increases the level of competence and helps to prevent disputes over findings. The Assessment Team Leader and the RQAM review assessment plans to ensure that the designated assessors have no direct involvement or responsibility for the work being assessed, and that there are no real or perceived conflicts of interest. In the case of peer review, assessment personnel (reviewers) are required to respond to a Conflict of Interest Inquiry to avoid any potential conflicts.

Responsibilities - Assessors' roles and responsibilities are described in the ***Assessment Program*** document. Assessors are responsible for the actual planning, conduct, evaluation, reporting, and documentation of assessments. They are also responsible for follow up to the assessments and evaluation of the response actions.

Authority - The authority to assess is derived from EPA Order 5360.1 A2. Assessment authority is confirmed in the planning stage for each assessment. For Quality System assessments performed by the QA Unit, the RQAM obtains concurrence of the senior management of the organization being assessed and documents this communication describing the purpose, scope and time frame for the assessment. For technical systems audits, the Lead Assessor and the Project Manager concur on the assessment's purpose, scope and time frame. These may be documented in a letter or in the final report for an assessment requested on short notice. Confirming the authority to assess in the planning stage of an assessment allows access to programs, managers, documents and records, and provides the organizational freedom to:

- identify both problems and noteworthy practices
- propose recommendations, and
- verify implementation and effectiveness of corrective actions.

9.4 Reporting and Response

Assessments conducted under the EPA NE Assessment Program must, by definition, produce a written report which summarizes the assessment, and States the findings and recommendations for response actions. Without documentation in a final report, a review or evaluation is not considered an assessment.

The objective of the report is to communicate assessment results to the responsible level of management. Efficient communication of results allows management to implement timely, effective response actions so that the quality objectives can be met. Quality System assessments are typically reported to senior managers of the organization responsible for the work. Assessments of project activities are reported to the EPA Project Manager. Copies of reports for internal assessments of project activities conducted by Lead Organizations also are sent to the EPA Project Manager. The EPA Project Manager may request a review of an audit report by the QA Unit. The process for reporting results of project assessments to EPA managers is described in Section 5.0, Key Components - Reporting, of the ***Assessment Program***.

Senior managers of the assessed organization are responsible for ensuring that any deficiencies found in Quality System assessments are appropriately addressed. Project Officers and Project Managers are responsible for ensuring that findings from assessments of project activities are appropriately addressed.

9.5 Corrective Actions

The process for corrective action in response to the findings of an assessment is described under Response Actions/Corrective Actions (Section 6.0) in the ***Assessment Program***. Essentially, the principal responsibility for the implementation of response/corrective action is that of the assessed organization. A written response is provided by the assessed organization for all assessment findings with objective evidence of the effectiveness of the correction, and with specified time frames for those actions in progress or planned for the future. For project activities, copies of all corrective action response letters and corrective action forms should be included as attachments to the QA Management Reports and included in the Final Project Report.

The authority and responsibility for verifying the timeliness and effectiveness of corrective action resides with the senior management ultimately responsible for the work that was assessed. The responsible senior manager may request the assessors who conducted the assessment to verify the effective implementation of corrective actions. Assessment follow up is documented and reported using the same process as the original assessment.

9.6 Dispute Resolution

If disputes are encountered as a result of assessments and related responses, then the dispute resolution process outlined in Section 1.3.9 of this QMP will apply.

9.7 Documentation and Tracking

The content requirements and recommended format for documenting and tracking assessments are presented in Section 7.0 of the ***Assessment Program***.

Assessment documentation includes:

- Assessment planning information including the criteria for the assessment,
- Checklist, questionnaire or other instrument for collecting and recording evidence,
- Assessment report,
- Follow up documentation verifying effective implementation of corrective action,
- Assessment file containing the response from the assessed organization, relevant communications and the documentation listed above.

EPA NE assessment activities are tracked in ATRACK, a tracking system that captures the following information for each assessment:

1) Project Name

2) Program
3) Type of Assessment
4) Subject of Assessment
5) Requester
6) Request Receipt Date
7) Assessment Team Members
8) Date Assessed (On-Site Visit)
9) Final Report Date
10) Corrective Action Recommendation
11) Corrective Action Completion Date (Documentation Received) and
12) Comments

9.8 Roles, Responsibilities and Authorities

The roles, responsibilities and authorities for assessment and response in EPA NE are described in the ***Assessment Program*** in Section 3.0 specifically and throughout the document. Among those defined are the roles, responsibilities and authorities for the following:

- Assessors
- Case Team
- EPA NE QA Unit
- Lead Organization
- Quality Managers
- Senior Managers

10.0 QUALITY IMPROVEMENT

EPA NE senior management is fully committed to quality improvement as a continuing process by which the organization actively seeks to identify opportunities to improve the overall Quality System. Quality improvement looks to correct systematic problems, improve consistency, enhance individual system components, re-engineer ineffective work processes and procedures, and customize quality tools. Quality improvement is incorporated as a core organizational element of EPA NE's quality culture and philosophy. Management and staff are encouraged to establish communications among themselves and with customers and suppliers to explore areas for improved service. EPA personnel are expected to identify areas for process improvement and to actively participate in problem solving.

As a critical component of the Regional Quality System, quality improvement provides an effective baseline for current and future Regional involvement in environmental data operations and environmental technology activities.

10.1 Annual Quality Management System Report

EPA NE is required under EPA Order 5360.1 A2 to report annually on the state of the Regional Quality System. This QA Annual Report provides an opportunity for the Region to identify areas of performance as well as components of the Quality System that require correction or improvement. The QAARWP serves to communicate major quality issues to EPA NE management. Based upon this report, senior management prioritizes workloads and allocates resources, as necessary, to address quality needs.

As discussed in Chapters 8 and 9, the RQAM will utilize both internal and external assessment findings to initiate quality improvement. Also, the RQAM will identify root causes of deficiencies; make recommendations for improvement; work with Regional management and staff to implement corrective actions; and subsequently evaluate the effectiveness of corrective actions in an overall effort to improve quality.

10.2 Organizational Improvement Based on Assessments

10.2.1 External Quality System Assessments

The Quality Staff of the Office of Environmental Information is responsible for conducting an assessment of the Regional Quality System at a minimum of every three years. In addition, national program offices may perform assessments of Regional programs. These assessments serve to periodically evaluate the effectiveness of the Quality System and quality-related procedures for Regional environmental programs, to help ensure consistency across the 10 Regions, and to identify

areas of needed improvement.

The results of Regional Quality System assessments are communicated to the Regional Administrator and the RQAM. The RQAM works directly with senior management to plan and implement corrective actions and modify the Quality System when and where appropriate. In addition, the RQAM may be involved in assisting Regional offices in responding to national assessments of their environmental programs.

10.2.2 Internal Quality System Assessments

In accordance with the Regional Assessment Program, at least one internal Quality System assessment is planned annually. The RQAM communicates the findings and results of internal assessments to the affected program managers. Criteria for internal assessments include:

- criticality of work performed;
- identified or suspected problem areas; and
- determining effectiveness of corrective actions or improvements to the Quality System.

As a follow-up to internal and external Quality System assessments, the RQAM plans assessments to ensure the effectiveness of corrective actions that were implemented and to evaluate improvements that have been made to the Quality System.

10.3 Responsibility for Quality Improvement

All EPA NE personnel are responsible for preventing quality problems whenever possible; identifying systematic problems in the Quality System; and reporting opportunities for improvement. Roles and responsibilities for identifying, planning, implementing and evaluating the effectiveness of quality improvement activities are interwoven throughout the fabric of the organization and have been discussed throughout this QMP. Regional policy requires the resolution of all issues that could potentially impact the quality of work and ultimately the environmental decision-making process. Problems/issues with immediate solutions should be resolved in an appropriate and timely fashion by program staff. All problems and corrective actions must be documented, and approved by the direct supervisor.

Problems/issues that require additional investigation to identify their cause may be referred to the QA Unit for evaluation. The QA Unit will evaluate the problem and determine if:

- the problem is an isolated non-conformance with Regional policies, requirements or procedures, or
- the problem is recurring, indicating a systemic problem requiring “re-engineering” of the

Quality System component, work processes and procedures, and/or training to prevent reoccurrence of system failures and deficiencies, or

- the problem is a result of inconsistent implementation of work procedures and Quality System processes. Historically, when "pockets" of inconsistent implementation are detected, Regional groups are convened to investigate the issue, make recommendations, implement process and procedural changes, and provide re-training.

In all cases, the QA Unit provides written reports that identify the quality issues and make recommendations for planning corrective actions, revising procedures and training. All corrections and/or modifications made to work processes and procedures are documented in new or revised standard operating procedures. It is management's responsibility to communicate to their staff identified problems and their resolution.

Enhancements to components of the Quality System are documented in revisions and amendments to the QMP. The QMP is reviewed annually to ensure that all information contained within it is relevant and up-to-date. Any necessary QMP revisions will be made, and revisions submitted to EPA's Quality Staff. Five years from the date of approval of this QMP, the RQAM will undertake a complete review of the document and submit a revised QMP to EPA Quality Staff for review and approval.

The approved Regional QMP will be posted on the EPA NE web site: http:///www.epa.gov/region01/topics/restech/qualsys.html. Quality system components and tools, including guidance documents and standard operating procedures, will also be posted on the EPA NE web site. Hard copies are available in the EPA NE library in Boston and at the Chelmsford satellite facility.

Appendix 1

U.S. ENVIRONMENTAL PROTECTION AGENCY
EPA NEW ENGLAND

MEMORANDUM

DATE: September 25, 2000

SUBJ.: Policy Statement Reaffirming EPA New England's Commitment to Implementing the Regional Quality System

FROM: Mindy Lubber, Regional Administrator
Ira Leighton, Deputy Regional Administrator

TO: EPA New England Employees

Our regional mission to protect human health and the environment hinges upon consistent application of sound science and the collection of credible data of the type and quality needed to support regulatory compliance, permit, enforcement, waste remediation and other critical program decisions. To support this mission, we are reaffirming EPA New England's commitment to:

- consistent and complete implementation of the regional quality system across all regional programs, as documented in the approved EPA NE Quality Management Plan,
- conformance with Agency quality policies as defined by EPA Order 5360.1, and
- compliance with Federal extramural agreement regulations pertaining to quality.

Background

EPA Order 5360.1 A2, *Policy and Program Requirements for the Mandatory Agency-wide Quality System* (current version dated 5/5/00), directs all Agency organizations to develop and implement a quality system that conforms to the requirements in the Order and in applicable extramural agreement regulations.

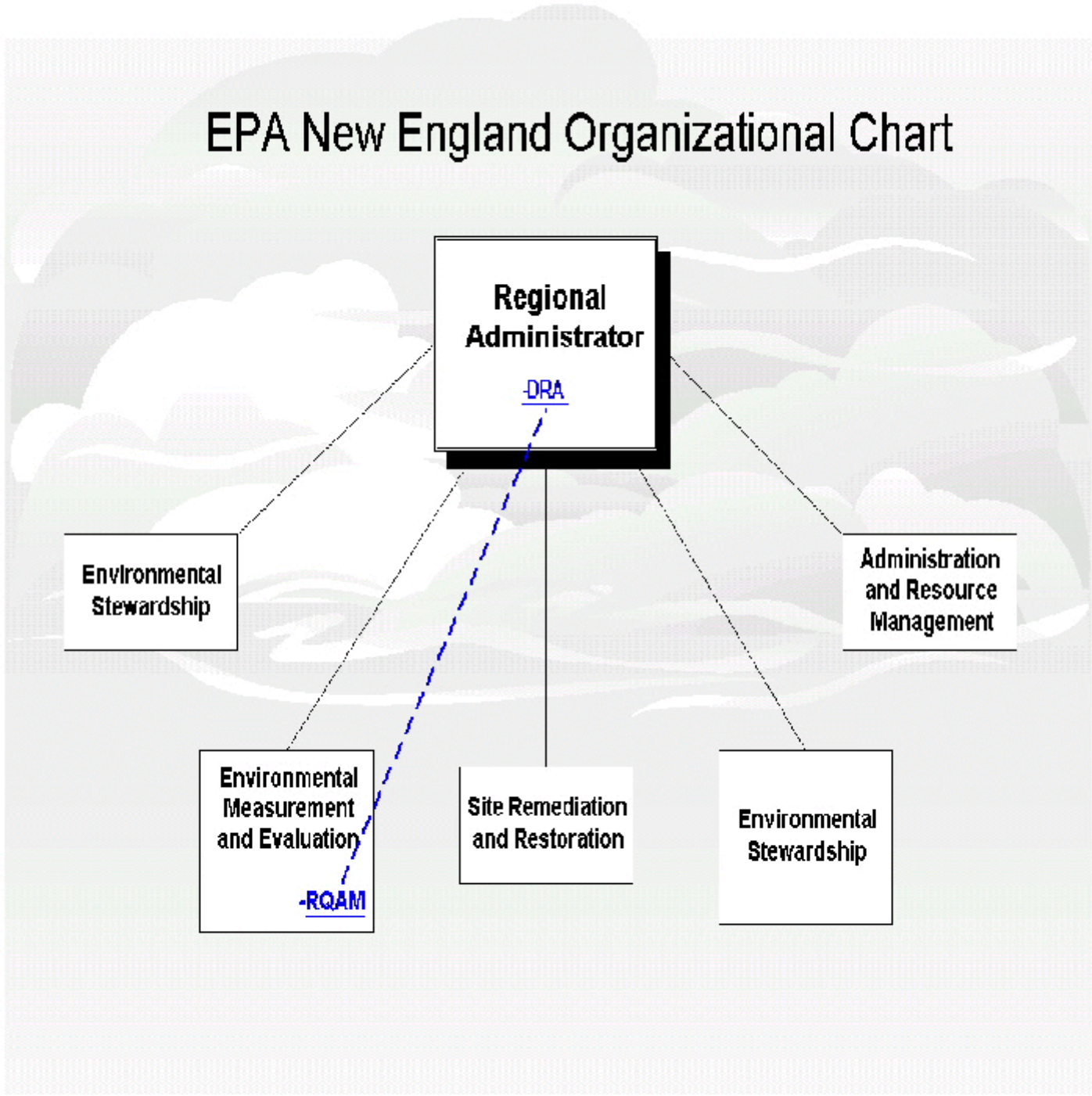
As part of the Agency's overarching quality system, the Quality Staff of the Office of Environmental Information conducts periodic assessments of all Agency organizations that collect, generate and use environmental data and that design, construct and operate environmental technology. The Quality Staff evaluated the EPA NE quality system this year and found that many elements of our regional quality

system were implemented effectively, however, there were "pockets" where implementation was not consistent or complete. The region has developed a corrective action plan to respond to the findings of this audit and are committed to resolving all the issues identified in a timely manner.

As part of our corrective action response, workgroups have been established to develop, document and implement written policies and procedures to address areas where Agency quality requirements have not been fully met. Senior management will identify and institute additional controls where necessary to assure that all environmental data operations and environmental technology activities performed by and for EPA NE are adequately planned, implemented and assessed in accordance with the Order. We look forward to your full support in implementing these procedures and in creating a culture that supports "continual quality improvement" within the region.

If you would like further information on the Agency's quality system, you can access fact sheets for frequently asked questions at www.epa.gov/quality1/qual_sys.html or contact Carol Wood at (781) 860-4316 or 8-4316.

Appendix 2


EPA New England Organizational Chart
Regional Administrator
-DRA
Environmental Stewardship
Administration and Resource Management
Environmental Measurement and Evaluation
-RQAM
Site Remediation and Restoration
Environmental Stewardship

Appendix 3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION I
OFFICE OF ENVIRONMENTAL MEASUREMENT AND EVALUATION
60 Westview Street, Lexington, MA 02173-3185

MEMORANDUM:

Date: September 6, 2001

Subj: Quality Assurance Requirements in Contracts and Procurements

From: Carol Wood, Acting Manager, Quality Assurance Unit
Stephen Perkins, Director, OARM

To: Region I Project Officers/Contracting Officer Representatives

This memo outlines the new Region I Quality Assurance procedures related to contracts/procurements and your role and responsibility in carrying out these procedures.

The Contracts Management Manual requires that all requests to contracting officers for placement of a new contract, a procurement (using simplified acquisition provisions), and an order (task order, work assignment, delivery order, etc.) under an existing contract, include a Quality Assurance (QA) Review form, completed by the project officer or other authorized contracting officer representative (COR). The purpose of this review form is to assure and document that appropriate quality assurance requirements are met for the products or services ordered.

1. New Contracts or Procurements

The Region I QA Review Form (see Attachment A) should be initiated by the appropriate COR prior to forwarding a request for placement of a new contract or procurement. (The COR is generally the "originator" on the PR Form.) The QA Review form will specify whether the products or services to be ordered require activities that involve environmentally-related measurements, and if so, upon consultation with the regional QA Manager or designee, what specific quality system requirements should apply. See Attachment B for examples of environmentally-related measurements.

In Part II of the QA Review Form, the COR shall indicate whether the proposed new contract/procurement requires activities that involve environmentally-

related measurements. If there are no environmentally-related measurements, the COR should sign the form and include it with the procurement request package. If the activities involve environmentally-related measurements, then the project officer or authorized COR shall complete Part III of the QA Review form. Part III of the form specifies what quality system requirements apply to the contract/procurement. This part should be completed upon consultation with the QA Manager or designee. Upon completion, the form should be signed by both the COR and the QA Manager or designee and then submitted as part of the procurement request package. The contracting officer shall incorporate the appropriate contract clauses applicable to the QA requirements specified in the QA Review form, as required in Procurement Policy Notice (PPN) 01-02.

2. Ordering Under Existing Contracts

When requesting services under an existing contract either through the issuance of a work assignment, task/delivery order or other ordering mechanism, the QA requirements specified in the approved QA Review form for the contract must be followed. Documentation of compliance with the required QA system requirements should be submitted to the QA Manager for each work order. This documentation will be defined on a contract-specific basis. Electronic notification is acceptable. Whether done electronically or hard copy, the contracting officer must receive this documentation for the official contract files.

3. Non-Regional Contracts or Procurements

While the attached QA Review form is a requirement for all contract and procurement actions issued by the Regional Contracting Officers, you should be aware that if you obtain products or services that involve environmentally-related measurements through a Headquarters contract, QA requirements still apply. In such cases, you should contact the appropriate Headquarters contracting officer or COR to determine whether QA requirements have been identified, or the regional QA Manager or designee for guidance on what QA requirements apply.

If you would like further information on the Agency's quality system or help in implementing this process, please contact Carol Wood at (617)918-8316 or visit the Agency Web site at www.epa.gov/quality/qa_docs.html.

Attachment A: QA Review Form
B: Examples of Environmentally-Related Measurements

cc: Supervisors

Regional Contracting Officers

Attachment A

REGION I QUALITY ASSURANCE REVIEW FOR EXTRAMURAL PROJECTS (CONTRACTS)

I. General Information

Descriptive Title: _____

Sponsoring Program Office: _____

Approximate Dollar Amount: _____

Duration: _____

II. This contract (or ordering document) requires activities that involve environmentally-related measurements.

[ ] YES [ ] NO

Percentage of technical evaluation points assigned to QA. _____%.
PO estimate of percentage of costs allocated to activities that involve environmentally-related measurements. _____%.

(*If YES, complete Section III, beginning on page 2 of this form, to specify the required quality assurance activities for this contract or ordering document; if NO, omit Section III and sign this form for submission with the procurement or ordering documentation.*)

The signature below verifies that the statement of work (SOW) of the contract or ordering document has been reviewed to determine if it requires activities that involve environmentally-related measurements.

_____

Project Officer/Contracting Officer Representative

_____

Date

III. Quality Assurance Requirements for Projects Involving Environmental Measurements

Use this form to provide direction to the Contracting Officer on the quality assurance activities that are required in the solicitation and contract.

1. a. Select all documentation required **before award of the contract:**

	Documentation	Specifications
9	Quality Management Plan	EPA Requirements for Quality Management Plans (QA/R-2) [dated 03/20/01]
9	Joint Quality Management Plan/Quality Assurance Project Plan	EPA Requirements for Quality Management Plans (QA/R-2) [dated 03/20/01] and EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]
9	Programmatic Quality Assurance Project Plan for the entire program (contract)	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]
9	Other Equivalent: _____	*[Insert specification]* _____

b. If the standard specifications do not apply, identify equivalent specifications: _____.

2. a. Select all documentation required **after award of the contract** or **issuance** of the specific work to be performed under the contract:

	Documentation	Specifications	Due After
9	Quality Management Plan	EPA Requirements for Quality Management Plans (QA/R-2) [dated 03/20/01]	Award of contract
9	Joint Quality Management Plan/Quality Assurance Project Plan	EPA Requirements for Quality Management Plans (QA/R-2) [dated 03/20/01] and EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]	Award of contract
9	Contract Quality Assurance Project Plan	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]	Award of contract
9	Programmatic Quality Assurance Project Plan for the entire program (contract)	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]	Award of contract

9	Quality Assurance Project Plan for each applicable project	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]	Issuance of statement of work
9	Project-specific supplement to Programmatic Quality Assurance Project Plan	EPA Requirements for Quality Assurance Project Plans (QA/R-5) [dated 03/20/01]	Issuance of statement of work
9	Other Equivalent: _____	*[Insert specification]* _____	*[Select one]* **9** contract award **9** SOW issuance

b. If the standard specifications do not apply, identify equivalent specifications: _____.

3. List any additional quality standards besides *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (ANSI/ASQC E-4)* that apply:

Title: _____
Numbering: _____
Date: _____

Documentation required to determine conformance: EPA QA/R-2, EPA Requirements for Quality Management Plans; EPA QA/R-5, EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations; Region I, EPA-New England Compendium of Quality Assurance Project Plan Requirements and Guidance; Region I, EPA-New England Quality Assurance Project Plan Manual; and Region I, EPA-New England Data Validation Functional Guidelines for Evaluating Environmental Analysis.

4. Other Quality Assurance Requirements

a. Performance on available audit samples or devices shall be required as part of the evaluation criteria. [ ] Yes [ ] No

b. An on-site evaluation of offeror's facilities will be made to ensure that a QA system is operational and exhibits the capability for successful completion of this project. [ ] Yes [ ] No

c. QA reports will be required. [ ] Yes [ ] No If yes, specify when: with progress reports _____; with the final report _____.

d. QA Systems Audits are required. [ ] Yes [ ] No If yes, specify when: pre-award _____; or during contract _____.

The signatures below verify that the contract or ordering document SOW has been reviewed to determine if it requires activities that involve environmentally-related measurements, an assessment of the QA requirements has been made, and the QA requirements have been established and agreed to as specified in Section III.

_____ _____

Quality Assurance Manager **Project Officer/Contracting Officer Representative**

_____ _____

Date **Date**

Attachment B

Examples of Activities involving Environmentally-Related Measurements

The following are some examples of activities that involve environmentally-related measurements that may be subject to higher-level contract quality requirements and the ANSI/ASQC E4 standard:

- Activities that collect data to establish/determine the states/conditions of environmental or ecological systems and the health of human populations;
- Activities that collect data to establish the ambient conditions in air, water, sediments, and soil in terms of physical, chemical, radiological, or biological characteristics;
- Activities that collect data to establish/categorize radioactive, hazardous, toxic, and mixed wastes in the environment and to establish their relationships with and/or impact on human health and ecological systems;
- Activities that monitor and quantify the waste and effluent discharges to the environment from processes and operations (e.g., energy generation, metallurgical processes, chemicals production), during either normal or upset conditions (i.e., operating conditions that cause pollutant or contaminant discharges);
- Activities that use environmental data to develop environmental technology for waste treatment, storage, remediation, and disposal; pollution prevention; and pollution control;
- Activities that use environmental data in mapping environmental process and conditions, and/or human health risk data, etc. (e.g., geological information system);
- Activities that generate data from the evaluation of environmental technology used for waste treatment, storage, remediation, and disposal; pollution prevention; and pollution control;
- Activities that generate/collect data to support enforcement and/or compliance

monitoring efforts;

- Activities that collect/generate data for the evaluation and/or demonstration of environmental technology (e.g., treatability and pilot studies);

- Activities that investigate and collect data to determine chemical, biological, physical, or radioactive constituents in environmental and ecological systems, and their behavior and associated interfaces in those systems, including exposure assessment, transport, and fate;

- Activities that collect and/or generate data from the development and evaluation of methods for use in the collection, analysis, and use of environmental data;

- Activities that involve the development, evaluation, and use of computers or mathematical models (and their input data) to characterize environmental processes or conditions;

- Activities that use secondary data (i.e., environmental data that were collected for other purposes or obtained from other sources, including literature, industry surveys, compilations from computerized data bases and information systems) for the development and/or evaluation of computerized or mathematical models of environmental processes and conditions, and collect/generate data from the process; and

- Activities that collect and/or use environmental data for monitoring/addressing concerns over the occupational health and safety of personnel in EPA facilities (e.g., indoor air quality measurements) and in the field (e.g., chemical dosimetry, radiation dosimetry).

Appendix 4

U.S. ENVIRONMENTAL PROTECTION AGENCY
EPA NEW ENGLAND

MEMORANDUM

DATE: January 25, 2001

SUBJ.: Revised Quality Assurance Requirements for Grants

FROM: Ira Leighton, Acting Regional Administrator

TO: Project Officers and Supervisors

A new grants process for the region is being implemented to insure that the region fully complies with Federal grant and cooperative agreement regulations pertaining to quality assurance and to correct one of the deficiencies identified in the recent EPA NE Quality System Audit report. These policies and procedures were developed by our Grants QA workgroup and agreed to by the Senior Leadership team.

The long-term process is currently being rolled out and includes 1) the development of training programs, 2) the delivery of training to insure that everybody knows their roles and has the technical knowledge to implement their responsibilities, and 3) a tracking system to document compliance with these requirements. A more detailed memo is being drafted and will be sent to the project officers shortly outlining their specific duties and responsibilities.

The project officers should continue to use the request for award memo to identify when QA is required. A set of standard grant conditions has been developed that the project officers, in consultation with the grants specialist, should utilize for all awards where quality assurance plans are required. Each office will have a QA representative, who, together with the Quality Assurance Office, will be available to provide advice and assistance to the project officer and the grants specialist in making the QA determination.

I would like to thank you in advance for your cooperation in implementing these procedures and in creating a culture that supports "continual quality improvement" within the region.

If you would like further information on the Agency's quality system or need help in implementing this process, please contact Carol Wood at (781) 860-4316 or 8-4316. You can access fact sheets for frequently asked questions at www.epa.gov/quality1/qual_sys.html

cc: Carol Wood, Acting RQAM
Office Directors and Deputy Office Directors

Appendix 5

U.S. ENVIRONMENTAL PROTECTION AGENCY
EPA NEW ENGLAND

Memorandum

Date: February 20, 2001
Subject: Requirements for Implementing New Quality Assurance Policies for Financial Assistance Agreements
From: Carol Wood, Quality Assurance Manager (QAM) and Pam Ringhoff, Grants Manager
To: Project Officers

The purpose of this memo is to explain new requirements for Project Officers' (PO) in implementing the new Quality Assurance (QA) policies and procedures for all financial assistance agreements (See Ira Leighton's memo of January 25, 2001, Attachment 1). An outline of the recently developed long-term Region 1 Grant QA Process is also attached (Attachment 2) for your reference. Training and technical support from the Office QA contacts (listed herein) and the QA Office will be available to assist PO's in implementing these new requirements.

The following are the key steps PO's are responsible for in order to insure compliance with these procedures.

Step 1 – Project Officer determines if a Quality Assurance Project Plan (QAPP) is needed. A "yes" or "no" decision must be made and then indicated on the "Assistance Agreement Request for Award/Action" memo. Your Office QA contact listed below must concur on all "no" decisions. The QA Office is also available for consultation and assistance as you make this decision.

ORA – Kristen Conroy
OES – Gerry Sotolongo
OSRR – Stan Chin
OEP - Robert Goetzl, Tony DePalma, Paul Bryan
OEME – Carol Wood
OARM – Pam Ringhoff

Note: EPA Order 5360.1 (May 2000, http://www.epa.gov/quality/qa_docs.html) outlines the Quality Assurance requirements for the agency and is applicable to the collection,

evaluation, and use of environmental data by or for EPA and the design, construction, and operation of environmental technology by EPA. A more detail discussion and training on what is included by this order will be given at a upcoming QA Awareness training within the next several months.

Step 2 – The Grants Specialist, based on the PO's QA determination listed on the Assistance Agreement Request for Award/Action, will incorporate the appropriate special grant condition(s) into the grant award. The special grant conditions are attached (Attachment 3). Although these conditions should address the majority of grants, a case by case review should be done by the Project Officer to insure that they are applicable to the specific grant. Any modifications to the special grant condition language must be reviewed and approved by the QAM.

Step 3 – Once the grant is awarded, the PO should work proactively with the grantee to insure that the QAPP is developed, completed and submitted to the QA Office for review and approval. The QA Office is available to help the PO discuss QA requirements with the grantee during development of the plan. In particular, for complex monitoring projects, a scoping meeting between the grantee, PO and QA representative is strongly recommended. Since the QAPP must be approved prior to the initiation of any monitoring activities , the QAPP must be submitted at least 30 days prior to the projected sampling date. Otherwise, work may be delayed pending the review and approval of the QAPP.

Additional Future Requirements

The Grants Quality Assurance Workgroup is in the process of developing additional items necessary to fully implement the attached long-term process. These items include the development of a system to track the grants QA requirements region wide and the development of a pre-application insert for the grants kits.

Your QA responsibilities as Project Officers will be discussed in more detail during the upcoming QA Awareness and QA Project Plan Program training courses. We welcome your comments and suggestions on this process and request that you send any specific questions that you would like to see addressed at the training course to Carol Wood. You may also direct any questions to your Office QA contact.

cc: Grants Specialist

Attachment 1

U.S. ENVIRONMENTAL PROTECTION AGENCY
EPA NEW ENGLAND

MEMORANDUM

DATE: January 25, 2001

SUBJ.: Revised Quality Assurance Requirements for Grants

FROM: Ira Leighton, Acting Regional Administrator

TO: Project Officers and Supervisors

A new grants process for the region is being implemented to insure that the region fully complies with Federal grant and cooperative agreement regulations pertaining to quality assurance and to correct one of the deficiencies identified in the recent EPA NE Quality System Audit report. These policies and procedures were developed by our Grants QA workgroup and agreed to by the Senior Leadership team.

The long-term process is currently being rolled out and includes 1) the development of training programs, 2) the delivery of training to insure that everybody knows their roles and has the technical knowledge to implement their responsibilities, and 3) a tracking system to document compliance with these requirements. A more detailed memo is being drafted and will be sent to the project officers shortly outlining their specific duties and responsibilities.

The project officers should continue to use the request for award memo to identify when QA is required. A set of standard grant conditions has been developed that the project officers, in consultation with the grants specialist, should utilize for all awards where quality assurance plans are required. Each office will have a QA representative, who, together with the Quality Assurance Office, will be available to provide advice and assistance to the project officer and the grants specialist in making the QA determination.

I would like to thank you in advance for your cooperation in implementing these procedures and in creating a culture that supports "continual quality improvement" within the region.

If you would like further information on the Agency's quality system or need help in implementing this process, please contact Carol Wood at (781) 860-4316 or 8-4316. You can access fact sheets for frequently asked questions at www.epa.gov/quality1/qual_sys.html

cc: Carol Wood, Acting RQAM
Office Directors and Deputy Office Directors

Attachment 2

Region 1 Long Term Grant QA Process - 2/12/01

QAPP Requirement Determination

> Project Officer (PO) determines if a QAPP is needed.

If yes, indicate requirement on the Assistance Agreement Request for Award/Action.

If no, obtain concurrence of Office QA contact.

> QA Office is available for consultation for above determination.

> QA Office will review a random sample of approximately 10% of the negative determinations and report the findings to management.

> The QAPP requirement is documented on the funding recommendation form.

The Project Officer will determine the appropriate special grant condition(s) and the Grants Specialist will incorporate into the grant award.

QAPP Preparation

> The PO will be proactive and provide on-going information and support to grantee(s) with assistance from QA Office.

> The PO will work with the grantee to understand the project and inform the grantee of QA requirements. The QAPP requirements will be commensurate with the complexity and intended use of the data.

> The Grants Office, based on the PO's QA determination listed on the Assistance Agreement Request for Award/Action, will send a post-award kit to the grantee that describes QAPP requirements and includes key EPA QA contacts (PO and QA Office).

> For large or significant grants it is encouraged to hold a scoping meeting or conference call to: determine data quality objectives, QA requirements to meet objectives, and content of QAPP. The PO determines if this is necessary and will coordinate the effort. Participants will include grantee, the PO, QA Office staff, and other participants identified by the PO or QA Office.

QAPP Approval

> Compliance with QAPP requirements is a shared responsibility between the PO and QA Office.

> PO has the lead to ensure QAPPs are submitted. The PO or designee can be delegated the completeness (Level 1) review responsibility as appropriate after QA training.

> QA Office conducts the technical (Level 2) review and approves the QAPP with the PO concurrence.

QA Tracking

> A QA tracking system will be developed to track and allow monitoring of requirements.
> Data maintenance will be a shared responsibility between Grants, the PO, and QA Office.

Note: If a QAPP is required and the grant is a continuing program grant, a Quality Assurance Management Plan (QMP) is also required. The QA Office will be responsible for approval of the QMP. The long-term strategy is to delegate QAPP approval to the states based on an approved QMP and documentation of capacity and capability to carry out this responsibility.

Attachment 3

Quality Assurance Grant Conditions for FY2001 - 2/12/01

A. If a grant is to be made to a State Environmental Agency with a PPA/PPG
[These are the organizations notified of QMP requirements by the RA's letter of 6/5/00]

[x] The State has developed its Quality Management Plan (QMP) and made a timely submittal of the QMP to EPA for review and approval. The State has submitted a schedule for development/revision of applicable Quality Assurance Project Plans (QAPPs). The grantee shall provide timely responses to written comments from EPA concerning its QMP and QAPP submittal. This award of financial assistance and any further assistance during the budget period is contingent upon adequate progress toward achieving approval of the QMP and implementation of the QAPP schedule as agreed to by the State and EPA. In addition, the grantee shall modify and update the QMP and QAPPs as necessary to assure consistency with the regulatory requirements and changes in protocols and/or procedures. Each submittal should be sent to:
- EPA Project Officer (see page 1 of assistance agreement for name and address) and
- Regional Quality Assurance Manager (EQA)
  U.S. Environmental Protection Agency
  60 Westview Street
  Lexington, MA 02421

B.1. If a Pesticides Program Grant is to be made to a State Agency with an approved QMP [CT, ME, MA, NH, VT]

INCLUDE BOTH CONDITIONS
[x] The State will review the existing Quality Management Plan (QMP) and provide a letter to the following:
- EPA Project Officer (see page 1 of assistance agreement for name and address) and
- Regional Quality Assurance Manager (EQA)
  U.S. Environmental Protection Agency
  60 Westview Street
  Lexington, MA 02421

documenting the review and accuracy of the QMP or submit a revised QMP within 1 year of the date of the existing QMP's approval.

[x] The State will develop a Quality Assurance Project Plan [QAPP] to support environmental data operations in accordance with *"EPA Requirements for Quality Assurance Project Plans"* (QA/R-5, 11/99) and/or the *EPA NE Compendium Of Quality Assurance Project Plan Requirements and*

Guidance, 10/99. The term "environmental data operations" refers to activities involving the collection, generation, compilation, analysis, evaluation and use of environmental data. The State will submit, by no later than 6/30/01, a Quality Assurance Project Plan (QAPP) to the following:
- EPA Project Officer (see page 1 of assistance agreement for name and address) and
- Regional Quality Assurance Manager (EQA)
U.S. Environmental Protection Agency
60 Westview Street
Lexington, MA 02421

B.2. If a Pesticides Program Grant is to be made to a State Agency without an approved QMP [RI]

INCLUDE BOTH CONDITIONS
[x] The State will submit the revised Quality Management Plan (QMP) within 30 days of the effective date of this assistance agreement to the following
- EPA Project Officer (see page 1 of assistance agreement for name and address) and
- Regional Quality Assurance Manager (EQA)
U.S. Environmental Protection Agency
60 Westview Street
Lexington, MA 02421.

[x] The State will develop a Quality Assurance Project Plan [QAPP] to support environmental data operations in accordance with *"EPA Requirements for Quality Assurance Project Plans"* (QA/R-5, 11/99) and/or the *EPA NE Compendium Of Quality Assurance Project Plan Requirements and Guidance*, 10/99. The term "environmental data operations" refers to activities involving the collection, generation, compilation, analysis, evaluation and use of environmental data. The State will submit, by no later than 6/30/01, a Quality Assurance Project Plan (QAPP) to the following:
- EPA Project Officer (see page 1 of assistance agreement for name and address) and
- Regional Quality Assurance Manager (EQA)
U.S. Environmental Protection Agency
60 Westview Street
Lexington, MA 02421

C. For other Continuing Program Grants not covered by A or B above:
[this includes State Agencies not covered in A, interstate organizations, and Tribal Governments. A special letter from EPA to these organizations will lay out QMP requirements]

INCLUDE BOTH CONDITIONS

[x] The recipient will develop and implement an ongoing quality system. The recipient will document this quality system in a Quality Management Plan (QMP) in accordance with "EPA Requirements for Quality Management Plans" (QA/R-2,11/99) and submit it to EPA for approval. Within 30 days of the effective date of this assistance agreement, the recipient will submit a schedule for the development of a QMP; the date for the submittal of the QMP will be no later than 9/30/01. Each submittal should be sent to the following:
- EPA Project Officer (see page 1 of assistance agreement for name and address) and
- Regional Quality Assurance Manager (EQA)
  U.S. Environmental Protection Agency
  60 Westview Street
  Lexington, MA 02421

[x] The recipient will develop Quality Assurance Project Plans [QAPPs] to support all environmental data operations in accordance with *"EPA Requirements for Quality Assurance Project Plans"* QA/R-5, 11/99 and/or the *EPA NE Compendium Of Quality Assurance Project Plan Requirements and Guidance,* 10/99. The term "environmental data operations" refers to activities involving the collection, generation, compilation, analysis, evaluation and use of environmental data. Within 30 days of the effective date of this assistance agreement, the recipient will submit a schedule for the development of all QAPPs. The recipient will submit the schedule for QAPP development to the following:
- EPA Project Officer (see page 1 of assistance agreement for name and address) and
- Regional Quality Assurance Manager (EQA)
  U.S. Environmental Protection Agency
  60 Westview Street
  Lexington, MA 02421

1.04 **For All Project Grants not included in A, B or C above:**

[x] The recipient will develop a Quality Assurance Project Plan [QAPP] to support all environmental data operations in accordance with "*EPA Requirements for Quality Assurance Project Plans*" (QA/R-5, 11/99) and/or the *EPA NE Compendium Of Quality Assurance Project Plan Requirements and Guidance, 10/99*. The term "environmental data operations" refers to activities involving the collection, generation, compilation, analysis, evaluation and use of environmental data. The Quality Assurance Project Plan must be approved by EPA before any data collection and/or generation activities begin. Within 30 days prior to the scheduled commencement of data collection and/or data generation activities, the recipient will submit a Quality Assurance Project Plan to the following:
- EPA Project Officer (see page 1 of assistance agreement for name and address) and
- Regional Quality Assurance Manager (EQA)
  U.S. Environmental Protection Agency
  60 Westview Street

Lexington, MA 02421

Appendix 6

U.S. ENVIRONMENTAL PROTECTION AGENCY
REGION I
OFFICE OF ENVIRONMENTAL MEASUREMENT & EVALUATION
60 WESTVIEW STREET, LEXINGTON, MA 02421-3185

MEMORANDUM

DATE: October 1, 1999

SUBJ: EPA-NE Quality Assurance Project Plan Policy

FROM: Nancy Barmakian
Quality Assurance Manager

TO: USEPA-NE Personnel and Parties Collecting, Generating and Compiling Environmental Measurements Under Regional Programs

The Region I, EPA-New England Quality Assurance Unit has restructured its Quality Assurance Project Plan (QAPP) Program in response to the recently reissued EPA Order 5360.1 CHG 1, 7/98. Among other requirements, this "QA Order" requires the development, review and approval of QAPPs for all environmental data operations performed by or on behalf of EPA prior to their initiation. In addition these requirements are incorporated into voluntary, consentual or unilateral enforcement agreements, decrees and orders.

EPA has developed the QAPP as an important tool for project managers and planners to document the type, quantity and quality of data needed to support environmental decision making. The QAPP describes the results of the planning process used to identify all technical and quality aspects for the life-cycle of the project including planning, implementation, documentation and assessment.

Purpose

The purpose of this memorandum is to officially implement the requirements of the restructured EPA-NE QAPP Program as specified in the ***Region I, EPA-New England Compendium of Quality Assurance Project Plan Requirements and Guidance*** document and its attachments (hereafter referred to as the *EPA-NE QAPP Compendium*). The ***EPA-NE QAPP Compendium*** is a regional implementation document for existing national requirements, including Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs, ANSI/ASQC E-4-1994; EPA Quality Manual for Environmental Programs, 5360, July 1998 and "EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations", EPA QA/R-5, October 1998, or latest revision.

Applicability

The requirements described in the ***EPA-NE QAPP Compendium*** apply to all environmental data operations performed on behalf of or funded by EPA-NE.

Specifically the ***EPA-NE QAPP Compendium*** applies to all environmental data operations conducted in EPA-NE by:

1. Contractors;

2. States, Tribes and local governments under financial assistance agreements, including grants and cooperative agreements;

3. Other Federal agencies under interagency agreements and Memoranda of Understanding with EPA-NE; and

4. Non-profit Organizations (e.g., volunteer organizations, interstate associations, etc.) under financial assistance agreements, including institutions of higher education and hospitals.

In addition, these QAPP requirements apply to the regulated community and shall be included in voluntary, consentual or unilateral enforcement agreements, decrees and orders.

Time frame

The October 1, 1999 implementation date marks the start of the transition period during which contractors and financial assistance recipients will conform with the requirements of the new ***EPA-NE QAPP Compendium***. In addition, the ***EPA-NE QAPP Compendium*** shall be included in new contracts as a “Higher-level Quality Standard”.

This implementation date also marks the date when the ***EPA-NE QAPP Compendium*** shall be included in all applicable voluntary, consentual or unilateral enforcement agreements, decrees and orders.

Any QAPPs that comply with the substance of E4-1994 and EPA QA/R-5 will continue to be approved by the EPA-NE QA Unit.

If you have any questions, please call me at (781) 860-4684 or Moira Lataille at (781) 860-4635.

Appendix 7

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION I
60 WESTVIEW STREET, LEXINGTON, MA 02173

MEMORANDUM

DATE: November 21, 1995

SUBJ: Development of EPA-NE Quality Assurance Training Modules

FROM: Moira M. Lataille, CLP-TPO Region I

TO: Nancy Barmakian, Quality Assurance Officer

In accordance with the QA Annual Report for FY'95, the QA office is continuing to develop its QA Training and Outreach programs for FY'96. Training materials will be developed that enable the QA office to train other EPA personnel and State, Local and Tribal partners. The training will complement the QA guidance that is now in effect and that which is currently being written.

Training modules will be developed for a number of QA related topics. Each training module will be assigned a two digit number, the first digit will identify the general QA subject while the second digit will be assigned in sequence of module development. The Region I modules may be stand alone training units or they may integrate the Quality Assurance Division (QAD) training modules that currently exist, i.e., DQO process-QAD Course Number 140 etc., or they may integrate training courses developed by commercial vendors, e.g. Immuno Assay Technology Transfers. I envision that most of the training will consist of several modules linked together.

The following numbers will identify specific training modules:

I. EPA-NE QUALITY ASSURANCE PROCESSES

10 EPA-NE QA Unit
- o Organizational Structure and Goals
- o Written Guidance
- o Affiliation with Quality Assurance Division (QAD)
- o Technical Assistance in field and method applications
- o QAPjP Reviews
- o Technical Systems Audits-Field Sampling, Fixed and field laboratory audits

- o Data Reviews
- o PE Sample Program
- o Management Systems Reviews (MSRs)
- o Self-Assessment Programs
- o Corrective Actions or Closing the QA Loop
- o QA Resources and References
- o Contract Administration of QA Support Contractors and Contract Laboratory Program

II. PLANNING

20 Scoping/Planning/DQOs
- o QAD DQO Course Numbers: 140,141,142, 143,241,242,243,244,245, 246,247,248,341,342,347 (including some environmental statistics that encompass both quantitative and qualitative approaches)

30 Quality Assurance Project Plans
- o QAD Course Numbers: 151, 251 and 252

40 EPA-NE Quality Assurance Plan

41 Removal Quality Assurance Program Plan

III. IMPLEMENTATION

50 Sampling
- o QAD Course Number: 445

51 Standard Operating Procedures
52 CLP Sampling Procedures
- o Preservation and Packing (TRs, etc.)

53 Sampling Scheduling under CLP and REAP

60 Analytical Methods
- o Choosing an analytical method

61 Detection Limits
62 Screening Methods
63 Innovative Technologies-new Methods

70 General Field and Laboratory QA

- Field QC samples
- Laboratory QC samples
- PARCC parameters

IV. ASSESSMENT

80 Data Validation

81 Introduction to the new "EPA-NE Data Validation Functional Guidelines for Evaluating Environmental Analyses"

- Description of new Document-Parts 1-IV
- Overview and Purpose of Data Validation
- Tiered Validation approach
- Comparison to old Functional Guidelines Guidance

82 Data Validation training for the experienced validator (in depth training with discussion of comparison of old and new FG guidance)

83 Data Validation training for the beginner (in depth training-no comparison discussion needed)

84 Performance Evaluation Sample Evaluation

- Availability and applicability of PES materials

85 Data Validation Training for the non-chemist

90 Data Quality Assessment (QAD Course Numbers: 191,291,391)

91 Interpretation of Data (QAD Course Number: 192)

92 Preparing for litigation (Utilizing course materials from the Expert Witness Training recently put on by the Air group)

Developing the Quality Assurance Training Modular
Program will be a cooperative team effort. Each member of our Quality Assurance Team will be able to provide added value to the evolution of specific modules. Over the next few months we should be able to develop the outline for many of these modules and begin training.

If you have any questions or would like to discuss this training plan, please feel free to contact me at (617) 860-4635.

ATRAIN.11M

Appendix 8

New England States
QUALITY MANAGEMENT PLAN
STATUS TABLE

(Updated: 09/10/01)

Organization	Type of Financial Agreement	Title, Revision Number and Date of Document	Current Status	Approval Date
CTDEP	Performance Partnership Grant	Connecticut Department of Environmental Protection Quality Management Plan - December 2000 Draft	Comment letter sent 03/29/2001	Pending
MADEP	Performance Partnership Grant	Quality Management Plan for Federally Funded Programs, Massachusetts Department of Environmental Protection, Effective Date 2001	Approved	10/2/01
MEDEP	Performance Partnership Grant	Maine Department of Environmental Protection Quality Management Plan Draft, Rev. No. 0, December 2000	Approved	05/24/2001
NHDES	Performance Partnership Grant	New Hampshire Department of Environmental Services Quality Management Plan, Revised: June 2001	Approved	07/03/2001
RIDEM	Performance Partnership Grant	Rhode Island Department of Environmental Management Bureau of Environmental Protection Quality Management Plan, December 29, 2000, Preliminary Draft	Comment letter sent 3/13/2000	Pending
VTDEC	Performance Partnership Grant	State of Vermont, Agency of Natural Resources, Department of Environmental Conservation Quality Management Plan - July 2001, Final	Approved	08/17/2001

Organization	Type of Financial Agreement	Title, Revision Number and Date of Document	Current Status	Approval Date
NH Department of Agriculture, Markets and Food	Categorical Grant	New Hampshire Division of Pesticide Control - Quality Management Plan, 01/21/2000	Approved	03/02/2000
ME Board of Pesticide Control Dept of Agriculture	Performance Partnership Grant	Quality Management Plan, Maine Board of Pesticide Control, January 2000	Approved	05/31/2000
MA Department of Food and Agriculture	Categorical Grant	Massachusetts Pesticide Bureau Quality Management Plan, May 2000	Approved	07/19/2000
VT Department of Agriculture, Food and Markets	Performance Partnership Grant	Vermont Department of Agriculture, Food and Markets Quality Management Plan, 08/01/2000	Approved	08/08/2000
CTDEP Pesticide Program	Performance Partnership Grant	Quality Management Plan, CTDEP, Pesticide Management Program, July 2000	Approved	07/26/2000
RIDEM/AGR Pesticide Program	Performance Partnership Grant	RIDEM/Division of Agriculture & Resource Marketing, Pesticide Program Quality Management Plan, Rev. No. 3, 03/29/2001	Approved	05/02/2001
CT Dept of Public Health	Categorical Grant		Letter sent Dec 13, 2000	
ME Dept. of Human Services	Categorical Grant		Letter sent Dec 13, 2000	
RI Dept of Health (RIDOH)	Categorical Grant		Letter sent Dec 13, 2000	

Organization	Type of Financial Agreement	Title, Revision Number and Date of Document	Current Status	Approval Date
MA Dept of Public Health	Categorical Grant		Letter sent Dec 13, 2000	
MA Dept. of Labor and Industries	Categorical Grant		Letter sent Dec 13, 2000	
MA Fire Marshall's Office	Categorical Grant			
NH Dept of Health and Human Services (DH DHHS)	Categorical Grant		Letter sent Dec 13, 2000	
VT Dept of Health	Categorical Grant		Letter sent Dec 13, 2000	

Appendix 9

CONTRACTS
EPA New England Quality Management Plan and Generic Program QAPP
STATUS TABLE
(Updated: 10/22/2001)

Organization	Type of Financial Agreement	Title, Revision Number and Date of Document	Current Status	Approval Date
Planners Collaborative, Inc./Resource Applications, Inc.	START 8(a) Contract	Quality Management Plan, August 2001	Approved	October 19, 2001
Planners Collaborative, Inc./Resource Applications, Inc.	START 8(a) Contract	Generic Quality Assurance Project Plan, August 2001	Approved	October 19, 2001
Lockheed Martin Systems Support & Technical Services (SS&TS)	ESAT Contract	ESAT Region 1 Quality Management Plan, Rev. No. 5, March 2001	Approved	June 20, 2001
Booz-Allen & Hamilton, Inc.	REPA2 Contract	Quality Management Plan for RCRA Enforcement, Permitting, and Assistance (REPA2) Contracts: Zone1 and Zone 3, Rev. No. 4, 05/29/2000	Comments on revision sent 6/15/2000	Pending
Booz-Allen & Hamilton, Inc.	REPA2 Contract	Quality Assurance Project Plan for the RCRA Enforcement, Permitting, and Assistance (REPA2) Contract: Zone 1-Region 1, 05/01/2000	Approved	June 27, 2000
Gannett Fleming	ROC Contract	Quality Management Plan Regional Oversight Contract, revised June 2001	Comment letter sent to Project Officer on 08/15/2001	Pending

Organization	Type of Financial Agreement	Title, Revision Number and Date of Document	Current Status	Approval Date
IT Corporation	ERRS Contract	Final Quality Assurance Project Plan for Emergency and Rapid Response Services (March 2000) Contract: 68-R1-98-01	Approved	April 4, 2000
Coastal Environmental Corporation	ERRS Contract	Quality Assurance Program Plan for Emergency and Rapid Response Services Contract Contract: PR-R1-99-10769	Comments sent to Project Officer on 08/29/01	Pending
Roy F. Weston, Inc.	START Contract	Quality Assurance Project Plan for Region 1 Superfund Technical and Response 2000 Contract, Draft, May 30, 2000. Contract: 68-W-00-097	8/01 Meeting to discuss revisions	Pending
TetraTech	REPA2 Contract	Quality Assurance Project Plan for the Region 1 Resource Conservation and Recovery Act (RCRA) Enforcement, Permitting, and Assistance (REPA2) Contract, Revision 1-003, 01/31/2000	Approved	April 25, 2000